

Cold Chain Breach or Excursion

Reporting form

In the event of a cold chain breach i.e. vaccine has been stored or transported in temperatures outside the 2-8°C range, immunisation providers must notify their Immunisation/Cold Chain Coordinator and seek advice about the stability and viability of the vaccine stock. With privately purchased vaccines it is recommended that HCL and/or the vaccine supplier is contacted. For more information, see Notes section.

This form gathers all the necessary information to ensure appropriate and timely advice can be provided.

Provider to complete and send (email or fax) to Immunisation/Cold Chain Coordinator.

ITEM	RESPONSE
Provider Name:	
PHO and/or DHB:	
Report date:	
Date and time of breach:	
Date and time breach discovered:	
Maximum temperature recorded:	
Minimum temperature recorded:	
Recordings from National Cold Chain monitors (if applicable):	
Refrigerator type/chilly bin:	
Date refrigerator/chilly bin was purchased:	
Date of refrigerator last service:	
What was cause of the breach? What went wrong? Why did it happen?	
What action has been taken by provider? What can be done to prevent it occurring again?	
Have any of the potentially compromised vaccines been administered?	YES / NO

Attach:

- printout of data logger recording covering the excursion (pdf or excel format)
- copy of daily min/max readings for last month
- list of vaccines, with batch number and expiry dates that are in the refrigerator.

Notes

Fluctuations in vaccine storage air temperature of up to 12°C lasting no longer than 30 minutes can occur when stock taking or restocking the refrigerator or as chilly bins warm during use before additional ice packs are added; these do not need to be reported. This rule does not apply to COVID-19 vaccine, all breaches above 8°C must be reported.

However, if you are getting repeated fluctuations e.g. more than one in a 24hr period or for unknown reasons, this must be discussed with your Coordinator.

Immunisation providers should not make any decisions about the use of vaccines following a cold chain breach until they have discussed the matter with their Coordinator, even if you had advice around a similar event in the past. The vaccines must be held in quarantine until the Coordinator has advised the provider of the thermostability review outcome and further actions to be taken (if required). The Coordinators have access to the most up to date thermostability information but they may still need to discuss the breach with the vaccine manufacturer, so decisions can take time.

Providers need to document any temperature fluctuations, the cause and any actions taken, there is a place for this either on the bottom of your daily minimum/maximum recording chart or in the cold chain history section of the Annual Cold Chain Management Record.

All cold chain excursions (where vaccines have been returned for destruction) are reported to the Ministry of Health (Ministry) by the Immunisation Advisory Centre (IMAC). These are reported by area rather than individual providers. The Coordinators and IMAC have a responsibility to report in a timely manner to the Ministry Immunisation Team if re-vaccination of patients is being considered as a result of a cold chain excursion.

Definitions of cold chain events

Cold chain breach – vaccines have been stored/ transported in temperatures outside the required range (+2°C to +8°C), but potency/stability not compromised.

Cold chain excursion – vaccines have been stored or transported in temperatures outside the recommended range (+2°C to +8°C) for a period of time that results in the vaccines being compromised. These vaccines need to be returned to Propharma for destruction.

Cold chain failure – vaccines that are involved in a cold chain excursion are subsequently administered to patients.

Regional Immunisation Advisors

Northern: lisa.box@auckland.ac.nz

Midlands: riamidland@auckland.ac.nz

Central: riacentral@auckland.ac.nz

Southern: riasouth@auckland.ac.nz

Midlands - COVID: olivia.haslam@auckland.ac.nz

Southern - COVID: sue.rogers@auckland.ac.nz

Immunisation/Cold Chain Co-ordinator to complete

Send along with provider information to IMAC Regional Immunisation Advisor (RIA).

All cold chain excursions must be reported to the IMAC RIA for your area. If the situation is complex e.g. multiple exposures to temperatures outside the 2-8°C range or patients have been given potentially compromised vaccines, then it is recommended that you make contact with the RIA ASAP to discuss the excursion and outline a plan of action.

ITEM	RESPONSE
Additional information accessed from the immunisation provider or vaccine company	
Action taken (examples): <ul style="list-style-type: none">• <i>Refrigerator fixed</i>• <i>Refrigerator replaced</i>• <i>Vaccines returned for destruction</i>• <i>Re-vaccination</i>• <i>Suspension of CCA</i>• <i>Education on Cold Chain for the Provider</i>	
How are you preventing it happening again?	
Vaccines returned for destruction	Number of doses (enter below)

Signature: _____

Name (print): _____

Designation: _____

CALL 0800 IMMUNE (466 863) for clinical advice