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| National Review of Cold Chain Management Practices: Summary and Recommendations | July 2016 |

## Overview

In December 2014, the Ministry of Health (the Ministry) commissioned PricewaterhouseCoopers (PwC) to undertake a review of cold chain management practices. This document is a summary of the key findings from the National Review of Cold Chain Management Practices.

The purpose of this review was to inform the update of the National Guidelines for Vaccine Storage and Distribution 2012 (the National Guidelines) and indicate if specific resources and training are needed to improve cold chain management processes and the transportation of vaccines to non-clinical settings (eg, schools, homes and workplaces).

**The cold chain**

Cold chain refers to the system of transporting and storing vaccines within the recommended temperature range of +2°C to +8°C from the place of manufacture to the point of vaccine administration. All immunisation providers, including general practices, pharmacists, school-based immunisation programmes and district health board (DHB) clinics/departments must maintain the cold chain at all times.

A cold chain failure occurs when vaccines are compromised or destroyed by freezing, being overheated or being exposed to direct sunlight/fluorescent light.

Cold chain management practices nationwide are based on the National Guidelines. All immunisation providers must achieve Cold Chain Accreditation (CCA) to ensure their cold chain management practices meet the minimum requirements for safe vaccine storage.

**Why review cold chain management practices?**

Cold chain management is dependent on the people involved, the equipment used and the management practices/processes in place. The cold chain involves multiple interactions that are especially prone to human error.

During 2013 and 2014, there were seven cold chain failures resulting in the re-immunisation of 327 individuals due to vaccine damage predominantly caused by human error. These failures affect families and the communities we are protecting. Cold chain failures are time consuming for the provider, DHB and the Immunisation Advisory Centre (IMAC) as well as expensive because the vaccines need to be replaced. Future cold chain failures also have the potential to undermine the public’s view of the National Immunisation Programme. The review’s key findings will assist in shaping cold chain management compliance strategies, improve cold chain processes and prevent future cold chain failures.

**Scope of the review**

The scope included review of:

* cold chain management practices of immunisation providers (ie, general practices, school-based immunisation programmes, DHB hospitals/wards/clinics/pharmacies, outreach immunisation services, community pharmacies and occupational health providers)
* the National Guidelines and associated materials
* CCA processes.

PwC conducted a provider survey (143 responses) and provider interviews (22), analysed the 2013/14 cold chain failure reports and reviewed national and international cold chain policies/practices.

Out of scope were the vaccine storage and distribution processes that precede vaccine delivery to immunisation providers (ie, the National Vaccine Store and regional distribution stores).

As part of their findings, PwC also analysed the National Cold Chain Audit (NCCA) data. The NCCA monitors the vaccine cold chain from the National Vaccine Store until vaccine administration by the provider. Although this analysis was out of scope and is not reported in this summary, the Ministry and PHARMAC have used this information to improve NCCA processes.

**International policies and practices**

The review of international cold chain policies/practices highlighted opportunities to improve cold chain management in New Zealand and it will be used to inform the review of the National Guidelines. For example, only using chilly bins for a maximum of eight hours, annual cold chain audits, enhanced cold chain failure reporting, use of portable refrigerators or validated medical grade chilly bins for off-site immunisation, annual cold chain training, twice daily minimum/maximum temperature recordings and weekly data logger downloads.

## Key findings

The following key findings identified the problem areas focusing on capability, process and technology (including equipment) and assisted in identifying potential solutions to the current cold chain issues and risks.

1. The use of many definitions to define a break in the cold chain (eg, failure, breach, excursion, cumulative damage) and the importance to be clear on the definition used.
2. A lack of insufficient data to accurately estimate cold chain failure costs as these include vaccine destruction and re-vaccination costs, resources to manage recalls/revaccination and the potential health costs associated with unprotected individuals.
3. Cases of cumulative vaccine damage going unnoticed, placing individuals at risk by compromised protection to disease.
4. Review of the cold chain before arrival at the provider was out of scope but was identified by providers as a significant issue (eg, courier deliveries) and an area for improvement in the future.
5. The process for receiving vaccines involved multiple individuals during the receipting process, causing the potential for cold chain failures as a result of staff absenteeism, lack of staff cold chain training, competing priorities and general delays.
6. Refrigerators continue to be a source of risk to vaccine integrity and temperature monitoring systems, resulting in cold chain failures. Issues highlighted included: ageing refrigerators, equipment failures, inconsistent refrigerator temperature monitoring practices and the absence of guidance on recommended specifications when purchasing new pharmaceutical refrigerators. Purchase and replacement were viewed by providers as being unsupported.
7. Chilly bins continue to be regarded as a source of risk. Issues included: chilly bins being prone to changes in ambient temperature; inconsistencies in temperature monitoring of the vaccines being stored and transported in chilly bins, and no standard chilly bin specifications.
8. Not all providers take appropriate action when they experience a cold chain failure, eg, fail to notify their immunisation coordinator, apply discretion in the use of the affected vaccines, have poor inventory management, are unclear of escalation procedures and lack access to vaccine stability data.
9. Cold chain support and materials vary between provider and regions, although there is little evidence to suggest a cold chain failure has occurred as a result of training.
10. The current CCA model lacks frequency and scope as it focuses on equipment and policies in a clinical setting and does not include the use of chilly bins and cold chain requirements for off-site clinics.

## Review recommendations

PwC identified the following solutions and provided the Ministry with recommendations based on their likely impact and ease with which they can be implemented. These solutions have been summarised below.

**Storage**

* Invite refrigerator suppliers to take a more active role in maintaining the cold chain (eg, lease refrigerators or service-based contracts on continuous reliability KPIs).
* Working with refrigerator suppliers to establish a national database of refrigerator stock would enable potential refrigerator failure cohorts to be sized and mitigated.
* 24/7 remote or web monitoring that transmit refrigerator temperatures and alarms to smart devices.
* Develop a basic factsheet outlining refrigerator specifications, performance, cost and suppliers.
* Put a fridge door self-closing check in the CCA process.

**Failure mitigation**

* Improve cold chain compliance by requiring all data loggers to be sampled at CCA (ie, readings outside the +2°C to +8°C range with no documented action will not pass CCA).
* Give immunisation coordinators access to up-to-date vaccine stability data.
* Use electronic vaccine stock management to assist forecasting and control stock levels.
* Formalise failure reporting to ensure responses are adequate and prevent future occurrences.
* Develop more comprehensive guidelines for managing breaches across a wide range of scenarios.

**Performance measures**

* Link NCCA process compliance to CCA.
* Reconcile vaccine order history with National Immunisation Register data and the vaccines returned for destruction.
* Establish regular performance reporting to the Ministry and individual providers (eg, costs of poor quality, revaccinations and sharing cold chain failure scenarios).

**Receiving vaccines**

* Consider using specialised cold chain couriers.
* Develop a vaccine training package for reception staff.
* Distinguish vaccine deliveries (eg, bright packaging and labelling).

**Off-site clinics**

* Develop a set of specifications for chilly bins, including packing guidelines.
* Price and test multiple chilly bin types (including plug-in ones) for use by outreach and school providers.
* Provide a list of preferred products (ie, chilly bins and temperature monitors with audible alarms) for use with chilly bins.
* Extend transportation guidelines to better mitigate environmental variables (eg, stored ice, car air conditioning, etc).
* Add chilly bin equipment and practises to the CCA process.

**Training, materials and support**

* Standardise information and support models.
* Consider a cold chain centre of excellence with a role in product support and centralised procurement.
* Define policies versus guidelines to reduce variation.
* Tailor policy/guidelines to providers.
* Use CCA to examine processes specific to the provider not just standard policies and equipment.
* CCA is only valid if the identified staff are present.
* Make CCA more frequent than three yearly.

## How the results will be used

Maintaining and improving cold chain management and compliance is a core component of the National Immunisation Programme. The Ministry accepts the findings provided by PwC to improve cold chain management practices and is working with PHARMAC and IMAC to consider and prioritise the review recommendations.

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