Government of **Western Australia**
Department of **Health**

Communicable Disease Control Directorate Guideline

Management of Cold Chain for Immunisation Service Providers

Guideline 0027 / 8 July 2025

Contents

Definitions / Acronyms

Term	Definition
AMS	Aboriginal Medical Service
ATAGI	Australian Technical Advisory Group on Immunisation
CAHS	Child and Adolescent Health Service
CCB	Cold Chain Breach
CDCD	Communicable Disease Control Directorate
°C	Degrees Celsius
DOH	Department of Health Western Australia
ECRG	Expert Clinical Review Group
EVS	Essential Vaccine Schedule
GP	General Practice
ISP	Immunisation Service Provider
NIP	National Immunisation Program
PHU	Public Health Unit
RIC	Regional Immunisation Coordinator – designated public health unit officer who promotes immunisation and responds to vaccine issues in their designated health region
SASA	Structured Administration and Supply Arrangements
VMP	Vaccine Management Protocol
WHO	World Health Organization

2. Purpose

The purpose of the Cold Chain Guidelines for Immunisation Service Providers, e.g. general practices, community pharmacies etc (the Guidelines) is to describe the cold chain-related policies and guidelines that apply to all Immunisation Service Providers (ISP) who provide immunisation services with government-funded vaccine and immunisation products in Western Australia (WA).

3. Introduction

The Australian Government provides WA with over $70 million in vaccines under the National Immunisation Program (NIP) each year. The responsibility to ensure the safe storage and use of these vaccines is on everyone who handles the vaccines. In addition, the state funds vaccines and monoclonal antibody products not on the NIP valued at over $15 million each year.

Vaccines are delicate biological substances that can become less effective if they are frozen, allowed to get too warm, and/or exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light.

Cold chain is a system of transporting and storing vaccines and other products such as monoclonal antibodies (mAb) within a recommended temperature range of +2° to +8°C. For the purpose of this guideline the term vaccine will be used but principles apply to other government-funded products such as Beyfortus. The temperature range has been endorsed by the World Health Organization (WHO)[1] and adopted by the Australian Technical Advisory Group on Immunisation (ATAGI) for the National Immunisation Program (NIP), as a guide to protect vaccines against loss of vaccine potency due to excessive cold or heat[2]. Cold chain starts from the time the vaccine is manufactured, continues throughout the transport to state or territory vaccine warehouses and on to ISPs, and ends when the vaccine is administered.[3] All ISPs play a vital role in maintenance of the cold chain to ensure the efficacy and safety of vaccines administered. Maintaining cold chain standards is crucial given the large number of vaccines stored within each practice/clinic and the cost attached to these vaccines.

The Communicable Disease Control Directorate (CDCD), WA Department of Health, is committed to best practice standards in the shipment, storage, and administration of vaccines. The CDCD is responsible, together with Public Health Units (PHUs) and ISPs, to monitor, review and implement the processes to ensure that all work is within the recommended standard of practice and maintain the efficacy of government-funded vaccines to minimise wastage. All WA immunisation providers and stakeholders responsible for the transport, storage and/or use of government-funded vaccines are required to adhere to the cold chain protocols provided by the WA Department of Health, the National Guidelines for Vaccine Storage – Strive for 5[3], and the Australian Immunisation Handbook[2] to ensure correct and consistent cold chain management.

[1] World Health Organization. (2006). Temperature sensitivity of vaccines. World Health Organization. Available from: https://apps.who.int/iris/handle/10665/69387
[2] Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018. Available from: https://immunisationhandbook.health.gov.au/
[3] Australian Government Department of Health (2019). National Vaccine Storage Guidelines. Strive for 5, 3rd edition. Commonwealth of Australia. Available from: https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

3.2 Governance

To receive government-funded vaccines, immunisation providers must comply with specific mandatory requirements to ensure that:

1. All vaccines received, stored and administered at the premises are recorded in the Australian Immunisation Register (AIR) (external site). New providers must complete the Australian Immunisation Register (AIR) - application to register as a vaccination provider form (IM004)
2. All vaccines received are stored and managed by staff who follow the National vaccine storage guidelines: Strive for 5 (external site), adhere to these Guidelines, are trained in cold chain management protocols, and complete the mandatory WA Department of Health eLearning Vaccine Storage and Cold Chain Management Training Module annually and report compliance using the Cold Chain Module Compliance Reporting form. If administrative or reception staff are responsible for receiving vaccines or checking fridge temperatures, they are also required to complete the module.
3. Providers ordering vaccines through Onelink are required to confirm they will adhere to recommended conditions for vaccine storage and management. Professionals who administer vaccines must meet the Educational Requirements for Immunisation Provision as set out in the Structured Administration and Supply Arrangements (SASA), have access to the current WA Immunisation Schedule and resources, and register for Vaccine Updates (external site).
4. Each account holder ensures their registration details are current for their premises, this includes evidence of the current poisons permit or AHPRA (external site) registration (for premises with one professional). Poisons permits or AHPRA registration details are recorded by the State's contracted warehousing and distribution provider, Onelink.
5. Each account holder ensures that any change of ownership, hours of operation, delivery address or any other account changes, including email address, are immediately advised to the Onelink customer service team and Vaccine Orders. This is important as these details are also used as a way to share important information including programmatic changes or updates.
6. Each account holder must commit to completing twice daily manual temperature recording as well as weekly data logger download and review to ensure temperature stability of their vaccine fridge containing government-funded vaccines is between 2° and 8°C. Confirmation of this action may be requested by the Department of Health at any time. There are no exceptions to this requirement.
7. Each account holder must provide evidence of a Vaccine Management Protocol (VMP) when requesting a new account. Provision of a VMP may be requested by the Department and must be provided at any time. Details about what should be included in a VMP can be found in Strive for 5, section 5.1.
8. Each account holder must complete an annual cold chain audit and provide this to the relevant PHU or at any time at the request of the WA Department of Health.
9. Each time an account holder orders vaccines they are required to agree to the terms and conditions for ordering government-funded vaccines, doing so indicates agreement and compliance with the terms and conditions.

3.2 Account suspension

An account suspension can be applied in any case of not complying with these guidelines, the Strive for 5 or an unresolved cold chain breach. Reactivation will only take place once supporting documents and any additional requested information are provided to finalise a cold chain breach. An account will be reactivated once approval by the RIC, or their representative has communicated the reactivation request to Vaccine Orders. Re-activation of accounts can take up to two weeks.

4. Monitoring and maintaining the cold chain process

4.1 Ordering vaccines

To order government-procured vaccines, ISPs must have an account with Onelink and follow the steps below:

1. Log in to your Onelink (external site) account to place your order.
2. When ordering, the 'stock on hand' (i.e., the vaccines currently in the ISP's refrigerator) must be recorded in the ordering form.
3. When a provider places a vaccine order, it is important to maintain appropriate levels of stock to meet the needs of the clinic/practice whilst also ensuring the refrigerator is not overcrowded. Read and accept the terms and conditions.
4. Enter delivery instructions if required. Note that orders are delivered Monday to Friday between 8.00 am and 5.00 pm.
5. Onelink customer service will review your order, and once it has been approved, a confirmation email is sent to your account email. Another email is sent once your order is dispatched. Note, if your poisons permit or registration details are not current, your order will be delayed.
6. Allow up to 3 business days for processing and delivery. Orders are not delivered to some regional areas on Mondays or Fridays. Deliveries may take extra time during public holidays.

There are periods in which the CDCD places ordering limits on specific products due to circumstances such as temporary limited stock or supply shortages.

Ordering information is available at Vaccine ordering (health.wa.gov.au).

4.2 Vaccines during transport

The WA Department of Health contracts Onelink to distribute vaccines to all WA providers from a central distribution warehouse based in Perth. For most providers, vaccine shipments are made directly from the vaccine warehouse to ISPs. The vaccine warehouse uses data loggers when transporting vaccines.

At times, an ISP may need to transport vaccines from one location to another. It is essential that good cold chain practices and the ISPs VMP are adhered to and documented when moving vaccines. When eskies are used to transport vaccines, they must be packed appropriately following the National Vaccine Storage 'Strive for 5' Guidelines section 9.3 'How to pack a cooler'.[3]

4.3 Vaccine deliveries

When vaccine orders arrive at the ISP premises, trained ISP staff must immediately:

1. Sign the delivery docket and return it to the courier.
2. Open the consignment, locate and stop the TagAlert data logger by holding the Start/Stop button for 5 seconds or until the stop sign icon appears. TagAlert data loggers must not be reused for subsequent trips if vaccines are moved to another location.
3. Check that the consignment order matches the delivery invoice, and if there is an unexplained discrepancy, email Onelink as soon as possible.
4. Follow the instructions on the 'Receiving vaccines: Reading a TagAlert® Monitor' form that is attached to the monitor.
5. At remote sites where the TempTale Ultra data logger is used, DO NOT DISCARD the data logger. The TempTale Ultra data logger must be returned to the WA Health warehouse using the postage-paid envelope that is included with the vaccine consignment. If you do not receive a postage-paid return envelope, please email Vaccine Orders. More information can be found on the TempTale factsheet.
6. Vaccines ***must not be removed from their original packaging*** as they are sensitive to light. They must remain in their original packaging until they are administered. This includes multi-pack vaccines. Ensure vaccines closest to expiration are stored at the front of the refrigerator.

Table 1. Actions for issues with vaccine delivery

Issue with vaccine delivery	**Action**
Vaccine damaged	Refer to Section 5 of the guidelines
Vaccine expired	Refer to Section 5 of the guidelines
Breach occurred during transport	• ISPs must complete the form attached to the TagAlert. • Take a photo of the TagAlert • TempTale Ultra data should be downloaded in table format. • Email form or data table to Onelink at customerservice@onelink.com.au. • **CDCD will provide stability advice to the PHU on transport breaches**.
Breach occurred at ISP premises (e.g., power outage, fridge failure)	ISPs must complete the CCB assessment form and send to their PHU no later than the next business day for prompt assessment of vaccines.

4.4 Vaccine management

Importance of vaccine management

Management of a data logger in the vaccine refrigerator and manual monitoring of refrigerator temperature are a requirement of receiving government-funded vaccines.

Vaccine management is a key performance indicator for all immunisation providers' accreditation. Records of twice-daily temperature recording, weekly data logger downloads and annual audits are to be kept for cold-chain assessment purposes. Failure to do so may result in a Providers vaccine ordering account being suspended.

Refrigerators

Domestic refrigerators (including bar fridges) are not designed to store vaccines and must not be used for vaccine storage.[3]

Blood refrigerators specifically designed to store blood products at a controlled temperature between +2°C and +6°C are acceptable to store vaccines and blood products together. Temperature monitoring that adheres with Strive for Five is still required.[3]

Purpose-built vaccine refrigerators or blood refrigerators should be serviced annually as per the manufacturer's guidelines. Documentation of the service should be retained by the provider and may be requested by the Department of Health as part of the audit process.

Manual temperature monitoring

The refrigerators' current temperature, and the minimum and maximum temperatures should be manually recorded twice daily (at the beginning and end of the clinic) on the minimum/maximum vaccine refrigerator temperature chart.[3] Copies of this temperature chart can be downloaded from the Australian Government Department of Health website or ordered for free from QuickMail. Changes in temperature outside the recommended range of +2°C to +8°C must be reported to the ISPs local PHU.

In some health facilities, vaccines are stored in the central pharmacy, ward, or clinic where central monitoring of temperature occur. Twice daily manual recording of temperature and weekly data downloads **are still a requirement** in these facilities as large cold chain breaches have been known to occur despite the automated central monitoring equipment.

Data loggers

The ability to measure temperature accurately and confidently within your refrigerator will determine whether the vaccines can be kept following a CCB. Government-funded vaccines should be stored in refrigerators that are regularly monitored. An accurate reading of temperature is essential to determine the temperature of vaccines in a vaccine refrigerator. Variations for common equipment include:

- Standard min/max thermometers (with a single digit display) usually have an error margin of ±1°C
- Data loggers can have an error margin of ±0.5°C or less.

ISPs must have data loggers within their refrigerator which will enable a detailed picture of the temperature excursions during a CCB to be examined and potentially prevent valuable vaccines from being discarded. At a minimum, data loggers should:

- Record at 5-minute intervals, and
- Be able to download a report in table or data view in pdf, gif, jpeg, tiff, excel or csv format.
- Be replaced as recommended by the manufacturer, if applicable, or the battery changed at the recommended intervals.

ISPs are encouraged to know the accuracy of the equipment within their refrigerator and to check the calibration/replace annually, or more frequently if there have been issues with the device. For advice on calibration of data loggers, refer to the manufacturer's directions on how to calibrate the data logger.

All newly installed vaccine refrigerators need to be monitored continuously with a data logger for at least 48 hours prior to use to ensure the refrigerator has a stable reading within the recommended range of +2°C to +8°C, striving for a temperature of +5°C.[3]

A back-up minimum/maximum thermometer or having two data loggers in the refrigerator is recommended. This will enable the refrigerator temperature to be assessed in the event of a power outage and may result in reduced vaccine wastage. In addition, a back-up thermometer or data logger provides an alternate reading in case of battery or technical failure of the primary data logger.

Transferring vaccines

In some circumstances, vaccines may need to be moved from one location to another, for example from a hospital pharmacy to a clinic, from one practice to another. While this activity introduces cold chain challenges, if required, it is essential that staff preparing, packing, delivering, and receiving the vaccines have completed the DOH eLearning Vaccine Storage and Cold Chain Management annually, and are familiar with their sites Vaccine Management Protocol. Details on transferring vaccines can be found in section 4.2.

Staff education

ISPs are responsible for ensuring all of their staff are educated in vaccine management, including how to appropriately store vaccines, read and record daily refrigerator temperatures and reset data loggers and vaccine refrigerator monitors and who can escalate breaches or cold chain issues to the appropriate PHU for advice. WA Primary Health Alliance (WAPHA) can support ISPs with the cold chain management education for staff. Refer to Immunisation Toolkit and/or the Immunisation@wapha.org.au for more information. WA Health has a staff education page with more information on available education material about cold chain management. RICs can provide education about cold chain when requested.

To facilitate staff education, a stand-alone eLearning Vaccine Storage and Cold Chain Management module must be completed by all staff involved in immunisation programs and vaccine management. This course will be required for all ISPs receiving government-funded vaccines and must be completed annually. Failure to compete will result in Onelink ordering accounts being suspended.

5. Cold chain breach

5.1 Cold chain breach management

The cold chain is a shared responsibility that begins from the time the vaccine is manufactured and ends when the vaccine is administered to the recipient (Table 3). Common breaches in the cold chain include refrigeration failure, power outage, overheating of vaccines during transportation, and/or freezing of vaccines. A cold chain breach (CCB) must be reported when the vaccines are exposed to:

- Any temperatures below +2°C for any length of time
- Temperatures above +8°C. This does not include temperature excursions in which the temperature reaches from +8°C up to a maximum of +12°C for 15 minutes or less as might be experienced when stocking the vaccine fridge. *Any cyclical excursions that are the result of faulty equipment must be reported every time.*
- Any light, such as opening and/or removal from packaging or damaged packaging and not administered as light penetrates through a glass fridge door.

  All CCBs that occur after delivery must be reported to the PHU in the region where the ISP is located.

Table 2. Process for reporting a cold chain breach or expired vaccine

Cold chain breach	**Action**
Vaccine expiry	Fill in the Vaccine Expiry Report Forms (health.wa.gov.au).
CCB or other (non-expiry) vaccine wastage	Fill in the information requested in the vaccine information report form Cold chain breach and vaccine wastage form (PDF). For any sites within metropolitan Perth, use Cold chain breach and vaccine wastage form (RedCap). For country WA sites, submit the form to your PHU.

Refer to the vaccine ordering webpage Vaccine ordering (health.wa.gov.au) for further information or contact your PHU,

Table 3. Roles and responsibilities

Communicable Disease Control Directorate	Public Health Unit	Immunisation Service Provider
Training and Education		
Develop and maintain the WA Department of Health Vaccine Storage and Cold Chain Management training module.	Promote the Vaccine Storage and Cold Chain Management training module with ISPs and are familiar with the WA Cold Chain Guidelines and the Strive for 5 with ISPs. Provide cold chain education and advice to ISPs.	Ensure all staff involved in handling government-funded vaccines complete the mandatory Vaccine Storage and Cold Chain Management training module and are familiar with the WA Cold Chain Guidelines and the Strive for 5 with ISPs.
Supply and Distribution		
Provide overall management of government funded vaccine distribution and supply in WA. Maintain and update the Terms and Conditions for ordering government-funded vaccines ensuring they are current and relevant. Provide relevant vaccination program communication to ISPs with important program information via registered email address and Vaccine Updates. Provide and update the WA Cold Chain Guidelines for ISPs.	Adhere to all terms and conditions for ordering government-funded vaccines. Promote the WA Cold Chain Guidelines and the Strive for 5 with ISPs.	Adhere to all terms and conditions for ordering government-funded vaccines. Ensure that email contact provided in the vaccine ordering account is up to date for receipt of important CDCD communications including program information. Develop a Vaccine Management Protocol.

Cold Chain Breaches		
Provide thermostability advice to PHUs. Liaise with PHUs and manufacturers when required.	Review and provide advice for each affected government funded vaccine involved in CCB and coordinate follow up action. If revaccination is required, may convene an Expert Clinical Reference Group for advice. *See section 5.2 Patient recall and revaccination.* Support cold chain audits with ISPs.	Report all cold chain breaches involving government-funded vaccines to your PHU. Provide requested information to the PHUs to assist with the assessment including additional information such as a photo of fridge or data logger download. Isolate (but do not discard unless instructed to) all vaccines involved in CCB to alternate +2°C to +8°C location and clearly label vaccines “Do not use”. Complete an annual cold chain audit.
Wastage		
Maintain a cold chain breach database.	Report all vaccine wastage to CDCD.	Report all government-funded expired vaccines via the expiry form here. Report all cold chain breaches. • Metropolitan Perth, use the online version here. • Country WA sites, submit the cold chain breach form to the relevant PHU.

5.2 Patient recall and revaccination

Recalling patients for revaccination following a CCB is rare but may be required if compromised vaccines are administered to patients. If revaccination is necessary, it will be undertaken by the ISP in consultation with the public health unit or immunisation expert. Where further advice is needed, the PHU may need to consult immunisation experts, or convene an Expert Clinical Review Group (ECRG) for advice. The CDCD should be notified about any complex or large-scale breaches where revaccinations are required. This process can be prevented by following good cold chain practices and reporting potential cold chain breaches promptly to the PHU.

6. Vaccine efficacy following a cold chain breach

6.1 Freezing

Many but not all vaccines are sensitive to freezing. Vaccines that are cold or freeze-sensitive can lose potency following a freeze event. It is important to get advice from the PHU on the stability of vaccines that have been frozen to ascertain whether they can still be used.

In all instances where vaccines are exposed to temperatures outside the recommended +2°C to +8°C temperature range, including those between 0°C and <2°C, must be reported to the PHU for advice on vaccine stability.

6.2 Heat

Heat impact on vaccines is often cumulative, therefore, vaccines exposed to temperature ranges over +8°C will, in many instances, still be able to be administered. When vaccines are exposed to repeated episodes of heat, the loss of vaccine potency is cumulative and cannot be reversed. Despite the robust thermostability of many vaccines, some do not tolerate heat.

In all instances where vaccines are exposed to temperatures outside the recommended +2°C to +8°C temperature range, ISPs are required to contact the PHU for advice on vaccine stability.

6.3 Light

Ultraviolet light can affect the stability of vaccines. All instances where the product is exposed to light prior to preparation for administration should be reported to the RIC. To prevent light exposure, vaccines **should not be** removed from the manufacturers packaging until ready to administer.

7. Document vaccine wastage

Vaccine wastage occurs because of many factors, such as refrigerator failure, power outages, CCBs during transportation, breakage, administering the wrong dose or incorrect vaccine to an individual (user error), or vaccine expiry.

Vaccines wasted through natural disasters, power outages and refrigeration failure (i.e., events beyond human control) are considered by the Commonwealth when calculating wastage incurred by each State and Territory.

It is important to report all vaccine wastage and the circumstances in which the wastage came about. Where vaccines are lost due to temperature excursions, regardless of any other reasons, cold chain breach should be selected as the reason for the loss of the vaccines.

7.1 Vaccine disposal

Vaccines that have expired should be discarded to prevent administering an expired vaccine. ISPs should do so using their local medical waste disposal procedures. Report expired vaccines to CDCD using the Vaccine Expiry Report Forms. If an expired vaccine has been inadvertently administered to a patient, the vaccine error must be reported to the Western Australia Vaccine Safety Surveillance System (WAVSS) and await advice on whether revaccination is required.

8. Guideline Contact

Enquiries relating to this Guideline may be directed to:
Immunisation Program
Directorate: Communicable Disease Control Directorate
Email: vaccineorders@health.wa.gov.au

9. Document Control

Guideline number	Version	Published	Review Date	Amendments
0027	V.1.0	8/07/2025	8/07/2027	Original version

10. Approval

Approved by	Dr Paul Armstrong Director Communicable Disease Control Directorate, Department of Health
Approval date	8 July 2025

11. Appendix list

Cold chain breach and vaccine wastage form (Regional WACHS sites)

Cold chain breach and vaccine wastage form (Metropolitan sites)

Managing a cold chain breach poster

This document can be made available in alternative formats on request for a person with disability.

health.wa.gov.au