

|  |  |  |
| --- | --- | --- |
| VMP Date: | Click to enter a date. |  |
| Name of Practice:  | Click to enter text. |
| Address:  | Click to enter text. |
| Suburb: | Click to enter text. | State: | Select | Post Code: | Click to enter text. |
| Phone: | Click to enter text. | Fax:  | Click to enter text. |
| Email: | Click to enter text. | *Click to insert company logo* |
|  |  |  |
| **Vaccine Service Provider (VSP) Number** | Click to enter text. |

This vaccine management protocol (VMP) has been developed based on the National Vaccine Storage Guidelines - Strive for 5 (3rd edition).

Vaccines should be stored in a purpose-built vaccine refrigerator (PBVR). Domestic refrigerators are **not** suitable for vaccine storage under any circumstance.

This document needs to be read in conjunction with [National Vaccine Storage Guidelines - Strive for 5](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) (3rd ed.).

Please ensure that a printed copy of this document is easily accessible for clinical staff. A copy should be located with your PBVR and all staff should be aware of its location.

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# Abbreviations

* CCB: Cold chain breach
* MSPHU: Metro South Public Health Unit
* PBVR: Purpose-built vaccine refrigerator
* QHIP: Queensland Health Immunisation Program
* VMP: Vaccine management protocol
* VSP: Vaccine service provider

# Introduction to vaccine management

**What is a cold chain and what is the definition of a cold chain breach?**

Cold chain refers to the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C. The cold chain begins from the time the vaccine is manufactured and only ends when the vaccine is administered.

A cold chain breach (CCB) occurs when vaccine storage temperatures deviate outside the recommended range of +2°C to +8°C. The optimal storage temperature for vaccines is +5°C. All vaccine temperatures recorded below +2°C or above +8°C must be reported to Queensland Health Immunisation Program (QHIP). This does not include temperature deviations in which the temperature reaches a maximum of up to +12°C for 15 minutes or less when conducting vaccine inventory or restocking. Any deviation below +2°C must be reported.

**Why is vaccine management important?**

Vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to warm or are exposed to direct sunlight or UV light, including florescent light.

**If we don't protect our vaccines - they won't protect our community.**

# Vaccine refrigerator/s

Our practice has the following PBVR that is fully compliant with the National Vaccine Storage Guidelines - Strive for 5 (3rd ed.), including:

|  |
| --- |
|  |
| **Fridge** Click to enter fridge number. |
|  | [ ]  Government funded vaccines OR [ ]  Government funded and private funded vaccines OR[ ]  Private vaccines  |
|  | Click to enter text. |
|  | Click to enter text. |  | Click to enter text. |
|  | Click to enter a date. |  | Click to enter a date. |
|  | Click to enter text. |  | Click to enter text. |
|  | Click to enter a date. |  | Click to enter a date. |
|  | Click to enter text. |
|  | The PBVR: |
| [ ]  |  |
| [ ]  |  |
| [ ]  |  |
| [ ]  |  |
| [ ]  |  |
| [ ]  |  |
|  |

# Staff

|  |  |
| --- | --- |
| Primary person responsible for vaccine management: | Click to enter text. |
| Secondary responsible person for vaccine management: | Click to enter text. |
| Person/role responsible for recording temperatures on opening: | Click to enter text. |
| Person/role responsible for recording temperatures on close: | Click to enter text. |
| Primary person/role responsible for ordering vaccines: | Click to enter text. |
| Primary person/role responsible for receiving vaccines: | Click to enter text. |
| Person responsible for orientating new staff: | Click to enter text. |
| Person responsible for annual staff education: | Click to enter text. |
| Person responsible for annual review of the VMP: | Click to enter text. |

# Vaccine ordering

* Government funded vaccines can be ordered from QHIP via fax 3328 9720 *or* via email QHIP-ADMIN@health.qld.gov.au
* Stocktake must be carried out before ordering new vaccines.

Identify:

|  |  |
| --- | --- |
| Where are order forms kept? | Click to enter text. |
| Who are they sent to? | Click to enter text. |
| How do you follow up on orders? | Click to enter text. |

**The aim when ordering vaccine is the right amount at the right time.**

# Receiving vaccines

Vaccines must only be received and signed for by staff educated in vaccine management appropriate for their designation. Vaccines are transported to vaccine service providers in refrigerated trucks – once removed from the truck they are no longer refrigerated and must be attended to immediately.

**The designated person is to:**

* Ensure vaccines are packed correctly
* Check heat sensitive indicator ensure that the cold chain has not been broken
* Transfer vaccines **immediately** to the vaccine refrigerator
* Check that the delivery is consistent with the order delivery docket
* Rotate stock – oldest expiring vaccines moved to the front and used first
* Minimise the time the vaccine refrigerator is open
* Record temperature and activity on the minimum / maximum temperature graph
* If there are any concerns about the vaccine delivery, vaccines are to be placed in the vaccine refrigerator, and QHIP is to be contacted immediately
* Temperature fluctuations up to +12.0°C lasting no longer than 15 minutes may occur when restocking. This does not constitute a cold chain breach and does not need to be reported.

**Packing the PBVR:**

* The vaccine refrigerator is **ONLY** for storing vaccines
* The refrigerator has the capacity to accommodate our vaccine storage needs without overcrowding stock (this includes seasonal influenza vaccines)
* Influenza vaccines are separated and clearly labelled into age appropriate groups that are stored in separate areas of the vaccine refrigerator
* All private vaccines are clearly marked and stored separate to the National Immunisation Program vaccines
* All vaccines are to remain in their original packaging
* It is best practice to store vaccines in open-weave plastic containers with a sold base. The container should be clearly labelled with names/s of the vaccines
* Ensure a ‘STOP’ sticker is clearly displayed on the door.

# Temperature monitoring and recording

All PBVR’s require a permanent data logger in place to continuously measure the temperatures at pre-set 5 minutely intervals. Monitoring requirements are as recommended by manufacturer and Queensland Health (varies with different brands of PBVR’s).

|  |
| --- |
| **Fridge** Click to enter fridge number. |
|  | [ ]  Data Logger [ ]  Inbuilt min/max |
|  | Click to enter text. |
|  | Click to enter a date. |
|  | Click to enter a date. |
|  | Click to enter text. |
|  | [ ]  Inbuilt thermometer [ ]  Datalogger |
|  | Click to enter text. |
|  | [ ]  Yes [ ]  No |
|  |
|  | Click to enter text. |
|  | Click to enter text. |
|  |

# Cold chain breach management

**Action in the event of a power outage – during business hours:**

1. Immediately isolate the vaccines
2. Keep vaccines refrigerated between +2°C and +8°C and label “do not use.” Vaccines may need to be transferred to an alternative PBVR or hard-shell cooler. NB: Never transfer to a domestic refrigerator.
3. Investigate the reason for the power failure:

If the cause is a power outage, phone the utility company to ascertain approximately how long the power will be interrupted.

|  |  |
| --- | --- |
| Power company and phone number: | Click to enter text. |

If the practice / clinic is part of a shopping centre or complex:

|  |
| --- |
| Centre management is aware of our PBVR and the requirements for continuous power |[ ]
| Centre management is aware of the requirement to inform the practice of any planned power outages |[ ]

If a safety switch (residual current device) has tripped, reset it. If it trips again, contact an electrician.

|  |  |
| --- | --- |
| Residual current device location: | Click to enter text. |
| Electricians contact details: | Click to enter text. |

1. Prepare a hard-shell cooler – see section 8 of this document or National Vaccine Storage Guidelines - Strive for 5 (3rd ed.), chapter 9
2. **Contact QHIP** on 3328 9888 / QHIP-ADMIN@health.qld.gov.au as soon as possible (i.e. next business day). Provide details on the cause, temperature range and your actions to date. QHIP will notify MSPHU of your CCB. A nurse from MSPHU will contact the reporting persons and provide recommendations.
3. Do not discard any vaccines until advised by MSPHU
4. For privately purchased vaccines, contact the manufacturer or supplier for thermostability advice.

**Actions in the event of a power outage – out of business hours:**

|  |
| --- |
| Click to enter text. |

**Backup plans in the event of a planned power outage:**

|  |
| --- |
| Click to enter text. |

**When the power is returned:**

* Record the minimum and maximum temperature of the PBVR and data logger
* Reset the thermometer (never reset until the temperatures have been recorded)
* Ensure the PBVR temperature has returned to between +2°C and +8°C prior to returning vaccines to the PBVR

**Power outage equipment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number of hard-shell coolers: | Click to enter text. | Is the cooler capacity adequate to store ALL vaccines in their original packaging?  | [ ]  Yes | [ ]  No |
| Total storage capacity of all hard-shell coolers (L): | Click to enter text. | Our clinic has adequate bubble wrap per cooler (roll or multiple sheets): | [ ]  Yes | [ ]  No |
| Number of portable thermometers *(1 per cooler and 1 per PBVR):*  | Click to enter text. | Our clinic has adequate number of frozen ice packs/gel packs located in the clinic: | [ ]  Yes | [ ]  No |
| Min/max monitoring charts are available for each hard-shell cooler: | [ ]  Yes | [ ]  No | Our clinic has ample empty vaccine boxes available for each portable thermometer: | [ ]  Yes | [ ]  No |
| Date of battery change: | Click to enter a date. | Next battery change due: | Click to enter a date. |
| Date of slush test: | Click to enter a date. | Next slush test due: | Click to enter a date. |
| Details on backup power supply *(if applicable) i.e. generator / uninterrupted power supply:* | Click to enter text. |
| *NB: A cooler is quickly filled when ice packs/gel packs, bubble wrap, loosely packed vaccines, a thermometer are placed within. Please obtain supplies to manage an outage when your PBVR is at its fullest i.e. the start of flu season.* |

**Maintaining monitoring equipment**

The accuracy of a minimum maximum thermometer is checked by performing a slush test, as described in the National Vaccine Storage Guidelines – Strive for 5 (3rd ed.), page 27. A slush test should be conducted after receiving a new thermometer, after changing a battery and at least every 12 months or sooner if the clinic is having cold chain problems. Replace the battery of the minimum/maximum thermometers at least every 12 months or sooner if suspecting thermometer issues.

# Preparing a cooler to store vaccines

**Conditioning ice packs**

* Remove ice packs from the freezer
* Lay out ice packs in a single row on their sides (where possible), leaving a 5cm space around each ice pack to allow maximum air exposure. This reduces the conditioning time
* Wait until ice packs begin to sweat. This will take up to 1 hour at +20°C
* The ice pack is conditioned as soon as water begins to ‘slosh’ about slightly inside the ice pack.

**Conditioning gel packs**

* Usually gel packs will take longer to condition than ice packs. Follow the manufacturer’s instructions for conditioning the gel pack. Although there is no ‘one rule fits all’ approach, there are some industry standards that can be used to guide conditioning if gel packs have been stored in the freezer at −20°C for a minimum of 36 hours. Conditioning frozen gel packs for the times prescribed below enables the initial chill factor to be removed from the packs.

**Guide to time needed to condition small and large gel packs:**

* Gel packs weighing less than 750g
* If ambient (room) temperature is over +15°C, condition for 45 minutes before use
* If ambient temperature is under +15°C, condition for 1 hour before use
* Gel packs weighing more than 750g
* If ambient (room) temperature is over +15°C, condition for 1 hour before use
* If ambient temperature is under +15°C, condition for 1½ hours before use.

**Packing a hard-shell cooler (maximum of 8-hour use)**

* One of the greatest risks to vaccines is freezing during transport in a cooler. The risk of freezing increases if the ice packs/gel packs are not correctly conditioned. Freezing episodes occur easily in all coolers, usually in the first 2 hours after packing. Monitor the temperature every 15 minutes for the first 2 hours, and then at least hourly.



*For further information, refer to National Vaccine Storage Guidelines – Strive for 5 (3rd ed.), pg. 64 - “how to pack a cooler”.*

**IMPORTANT:** Depending on the circumstances of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In these instances, use additional insulating material to protect the vaccine and monitor the portable cooler more frequently then outlined in step 10.

# Mobile or outreach clinics

If your clinic conducts mobile or outreach immunisation clinics, please outline your procedure:

|  |  |
| --- | --- |
| Preparation for the clinic *(See National Vaccine Storage Guidelines - Strive for 5, appendix 7):* | Click to enter text. |
| Vaccine monitoring during session*(See National Vaccine Storage Guidelines - Strive for 5, appendix 8):* | Click to enter text. |
| Returning remaining vaccines to the PBVR*(See National Vaccine Storage Guidelines - Strive for 5, appendix 8):* | Click to enter text. |

# Vaccine storage self-audit

Immunisation service providers are required to carry out a vaccine storage [self-audit](https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5-appendix-2-vaccine-storage-self-audit_0.pdf) at least once every 12 months, and more frequently if there have been problems with equipment or CCB. Documentation should be stored for future reference and may be requested as part of a CCB investigation by the MSPHU.

|  |  |
| --- | --- |
| Vaccine storage self-audit conducted on: | Click enter a date. |
| Vaccine storage self-audit due: | Click enter a date. |

**Please ensure that a printed version of this policy is located with the PBVR and that all staff are**

**aware of its location and content.**

**Refer to *National Vaccine Storage Guidelines - Strive for 5 (3rd edition),* in conjunction with the VMP.**

|  |  |  |
| --- | --- | --- |
| Nominated person responsible for vaccine management: | Principal General Practitioner: | Practice Manager: |
| Name: | Click to enter text. | Name: | Click to enter text. | Name: | Click to enter text. |
| Signature: |  | Signature:  |  | Signature: |  |
| Date: | Click to enter a date. | Date: | Click to enter a date. | Date: | Click to enter a date. |