Queensland Health

Vaccine Management Protocol

Queensland Immunisation Program



Vaccine Management Protocol - Queensland Immunisation Program

Published by the State of Queensland (Queensland Health), January 2023 This document is licensed under a Creative Commons Attribution 3.0 Australia licence.



To view a copy of this license, visit creativecommons.org/licenses/by/3.0/au

© State of Queensland (Queensland Health)

You are free to copy, communicate and adapt the work, as long as you attribute the State of Queensland (Queensland Health).

For more information contact:

Please contact your local <u>Public Health Unit</u> for any information or advice.

Immunisation Program, Queensland Health, GPO Box 48, Brisbane QLD 4001, email immunisation@health.gld.gov.au

More Vaccine Service Provider information is available at https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/service-providers

Contents

1	Vaccine refrigerator/s	5
2	Staff	10
<u>3</u>	Vaccine ordering	10
<u>4</u>	Receiving vaccines	11
<u>5</u>	Temperature monitoring and recording	12
6	Cold chain breach management	22
7	Preparing a cooler to store vaccines	25
8	Mobile or outreach clinics	27
9	Vaccine storage self-audit	27
Αį	ppendix 1	28
Υe	ellow Fever Vaccination Provider	28
De	ocument approval details	29
Do	ocument custodian	29
Αŗ	pproval officer	29
Αŗ	pproval date:	29
Ve	ersion control	29

VMP Date:							
Name of Provider:							
Address:							
Suburb:			State:		Post Code:		
Phone:				Fax:			
Email:				Click to insert company logo			
PHU:	PHU ONLY						
Date approved:	PHU ON	ILY	Date rev	view is due:	Р	HU ONLY	

Vaccine Service Provider (VSP) Number

It is a requirement for VSPs to have an up-to-date Vaccine Management Protocol (VMP) lodged with their respective Public Health Unit. VSPs without a current VMP will not be eligible to receive vaccine from the Queensland Health Immunisation Program.

Please contact your local Public Health Unit for any information or advice.

This VMP template has been developed based on the National Vaccine Storage Guidelines – Strive for 5 (3rd edition) National Vaccine Storage Guidelines 'Strive for 5' | Australian Government Department of Health and Aged Care. This template aims to assist VSPs in developing a VMP in collaboration with your local public health unit (PHU) that reflects their current vaccine storage and management process. Reasons for developing and updating a VMP include (but are not limited to):

- changes to staff responsible for vaccine management.
- newly purchased, moved or repaired purpose-built vaccine refrigerator (PBVR).
- updates to equipment service dates, staff training (both new and existing) or audit dates.
- 12 months since the last review of the VMP by the respective Public Health Unit.

Please ensure that a printed copy of the VMP is easily accessible for staff involved with vaccine management. A copy should be co-located with the VSP's PBVR and staff should know its location.

This document needs to be read in conjunction with National Vaccine Storage Guidelines Strive for 5 (3rd edition) (NVSG) which can be downloaded from:

https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strivefor-5

1 Vaccine refrigerator/s

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

Make/brand of PBVR (Fridge	1)			
The Primary purpose of PBVI	₹:			
☐ Government Funded vacc	ines $\;\;\square$ Government funded and privately f	^F unded □ Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & freq	uency: (Monthly cleaning during stocktake is re	commended)		
Position & maintenance of PBVR: ☐ is away from warm external walls and out of direct sunlight ☐ is in a secure area only accessible to staff ☐ is positioned to enable sufficient air circulation around the back and sides ☐ power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the power source is exposed, a switch cover is necessary ☐ has onsite access to a separate freezer for storage of gel packs/ice bricks ☐ has an audible alarm system. Recommended to test monthly				
Make/brand of PBVR (Fridge 2)				
The Primary purpose of PBVI	₹:			
☐ Government Funded vacc	ines □ Government funded and privately f	funded \square Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency: (Monthly cleaning during stocktake is recommended)				
Position & maintenance of PBVR: □ is away from warm external walls and out of direct sunlight □ is in a secure area only accessible to staff □ is positioned to enable sufficient air circulation around the back and sides □ power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the power source is exposed, a switch cover is necessary □ has onsite access to a separate freezer for storage of gel packs/ice bricks □ has an audible alarm system. Recommended to test monthly				

Make/brand of PBVR (Fridge	3)				
The Primary purpose of PBVI	₹:				
☐ Government Funded vacci		funded □ Private va	ccines		
Model of PBVR		Size of PBVR			
Purchase date		Warranty expiry date			
Name of service contractor		Phone number			
Date of last service		Next service date			
Cleaning Instructions & frequency	uency: (Monthly cleaning during stocktake is r o	ecommended)			
Position & maintenance of P	BVR:				
\square is away from warm extern	nal walls and out of direct sunlight				
\Box is in a secure area only a	ccessible to staff				
\square is positioned to enable s	ufficient air circulation around the back and	sides			
	clearly to prevent the PBVR from being accid	dentally unplugged or to	urned off. If the		
	a switch cover is necessary				
	parate freezer for storage of gel packs/ice b	ricks			
☐ has an audible alarm sys	tem. Recommended to test monthly				
Make/brand of PBVR (Fridge 4)					
The Primary purpose of PBVI	₹:				
☐ Government Funded vacci	ines \square Government funded and privately	funded 🗆 Private va	ccines		
Model of PBVR		Size of PBVR			
Purchase date		Warranty expiry date			
Name of service contractor		Phone number			
Date of last service		Next service date			
Cleaning Instructions & frequency: (Monthly cleaning during stocktake is recommended)					
Position & maintenance of PBVR:					
☐ is away from warm external walls and out of direct sunlight					
☐ is in a secure area only accessible to staff					
☐ is positioned to enable sufficient air circulation around the back and sides					
power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the					
	power source is exposed, a switch cover is necessary				
	parate freezer for storage of gel packs/ice b	ricks			
\square has an audible alarm system. Recommended to test monthly					

Make/brand of PBVR (Fridge	5)			
The Primary purpose of PBVF	₹:			
☐ Government Funded vacci	ines Government funded and privately	funded \square Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequ	uency: (Monthly cleaning during stocktake is r o	ecommended)		
Position & maintenance of P	BVR:			
☐ is away from warm extern	nal walls and out of direct sunlight			
☐ is in a secure area only a	ccessible to staff			
\square is positioned to enable s	ufficient air circulation around the back and	sides		
	clearly to prevent the PBVR from being accid	dentally unplugged or to	urned off. If the	
	a switch cover is necessary			
	parate freezer for storage of gel packs/ice b	ricks		
☐ has an audible alarm sys	tem. Recommended to test monthly			
Make/brand of PBVR (Fridge 6)				
The Primary purpose of PBVF	₹:			
☐ Government Funded vacci	ines \square Government funded and privately	funded 🔲 Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency: (Monthly cleaning during stocktake is recommended)				
Position & maintenance of PBVR:				
☐ is away from warm external walls and out of direct sunlight				
☐ is in a secure area only accessible to staff				
☐ is positioned to enable sufficient air circulation around the back and sides				
power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the				
power source is exposed, a switch cover is necessary				
	parate freezer for storage of gel packs/ice b	ricks		
\square has an audible alarm system. Recommended to test monthly				

Make/brand of PBVR (Fridge	7)			
The Primary purpose of PBVI	₹:			
☐ Government Funded vacci		funded □ Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency	uency: (Monthly cleaning during stocktake is r o	ecommended)		
Position & maintenance of P	BVR:			
\square is away from warm extern	nal walls and out of direct sunlight			
\Box is in a secure area only a	ccessible to staff			
\square is positioned to enable s	ufficient air circulation around the back and	sides		
	clearly to prevent the PBVR from being accident	dentally unplugged or t	urned off. If the	
	a switch cover is necessary			
	parate freezer for storage of gel packs/ice b	ricks		
☐ has an audible alarm sys	tem. Recommended to test monthly			
Make/brand of PBVR (Fridge 8)				
The Primary purpose of PBVI	₹:			
☐ Government Funded vacci	ines $\ \square$ Government funded and privately	funded 🗌 Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency: (Monthly cleaning during stocktake is recommended)				
Position & maintenance of PBVR:				
☐ is away from warm external walls and out of direct sunlight				
☐ is in a secure area only accessible to staff				
☐ is positioned to enable sufficient air circulation around the back and sides				
power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the				
power source is exposed, a switch cover is necessary				
	parate freezer for storage of gel packs/ice b	ricks		
\square has an audible alarm system. Recommended to test monthly				

Make/brand of PBVR (Fridge	9)			
The Primary purpose of PBVF	₹:			
☐ Government Funded vacci	ines Government funded and privately	funded \square Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency	uency: (Monthly cleaning during stocktake is r e	ecommended)		
Position & maintenance of P	BVR:			
☐ is away from warm extern	nal walls and out of direct sunlight			
☐ is in a secure area only a	ccessible to staff			
\square is positioned to enable s	ufficient air circulation around the back and	sides		
	clearly to prevent the PBVR from being accid	dentally unplugged or to	urned off. If the	
	a switch cover is necessary			
·	parate freezer for storage of gel packs/ice b	ricks		
☐ has an audible alarm sys	tem. Recommended to test monthly		_	
Make/brand of PBVR (Fridge 10)				
The Primary purpose of PBVF	₹:			
☐ Government Funded vacci	ines $\ \square$ Government funded and privately	funded 🗌 Private va	ccines	
Model of PBVR		Size of PBVR		
Purchase date		Warranty expiry date		
Name of service contractor		Phone number		
Date of last service		Next service date		
Cleaning Instructions & frequency: (Monthly cleaning during stocktake is recommended)				
Position & maintenance of PBVR:				
☐ is away from warm external walls and out of direct sunlight				
☐ is in a secure area only accessible to staff				
☐ is positioned to enable sufficient air circulation around the back and sides				
power source is labelled clearly to prevent the PBVR from being accidentally unplugged or turned off. If the				
power source is exposed, a switch cover is necessary				
	parate freezer for storage of gel packs/ice b	ricks		
□ has an audible alarm system. Recommended to test monthly				

2 Staff

Activity	Person responsible AND role (job title)
Primary person/role responsible for vaccine management*	
Secondary responsible person/role for vaccine	
management*	
Recording temperatures at the start of a business day*	
Recording temperatures at the close of a business day	
Ordering vaccines*	
Receiving vaccines/Checking vaccine expiry dates and	
rotating stock*	
Orientation for new staff*	
Annual staff education	
Current (within 12 months) certification of training	
undertaken for all staff responsible for cold chain	
management available**	
Annual review of the VMP*	

^{*}Use position titles first rather than names

3 Vaccine ordering

- Government funded vaccines can be ordered from the Queensland Health Immunisation Program (QHIP) via email: QHIP-ADMIN@health.qld.gov.au
- Download and complete the Immunisation Program Vaccine Order Form
- Vaccine order must include:
 - o Confirmation that vaccines have been stored between +2°C to +8°C.
 - o The order date and VSP number.
 - The provider's details (name, delivery address, email address, telephone number and fax number).
 - A stocktake identifying the quantity of each vaccine, their expiry dates and the quantity required for any additional vaccines.
- Advise QHIP if the provider will be closed when delivery is expected (e.g. public holidays) and arrange a suitable delivery time.

Ordering is completed (e.g. first week of each month)	

^{**}See-<u>online courses for immunisation service providers</u> (Minimum requirement is Course 4 - Vaccine Management (health.qld.gov.au)

4 Receiving vaccines

Vaccines must only be received and signed for by staff educated in vaccine management. Vaccines are transported to VSPs in either refrigerated transport or packed in transport eskies/shippers. For those vaccine deliveries that arrive via refrigerated transport, these must be attended to, receipted, and moved into the PBVR immediately.

The designated person is to:

- Ensure vaccines are packed correctly.
- Check heat sensitive indicator to ensure that the cold chain has not been broken.
- If included: Check the Cold Mark Monitor (CMM) for any change in colour from clear. If any colour detected, complete the Queensland Health Immunisation Program Vaccine
 Deliveries Issues Reporting form and email to QHIP-ADMIN@health.qld.gov.au
- Provide photographic evidence of the CMM and or time-temperature bullseye with the delivery issues form.
- Transfer vaccines immediately to the PBVR.
- Check that the delivery is consistent with the order delivery docket.
- Rotate stock so that oldest expiring vaccines are moved to the front and used first.
- Minimise the time that the PBVR is open.
- Temperature fluctuations <u>up to</u> +12.0°C lasting <u>no longer than</u> 15 minutes may occur when restocking. This does not constitute a cold chain breach and does not need to be reported.
- Record temperature and activity on the minimum/maximum temperature graph.
- If there are any concerns about the vaccine delivery, vaccines are to be placed into the PBVR and contact QHIP immediately.

Packing the PBVR:

- The PBVR is ONLY for storing vaccines.
- All vaccines are to remain in their original packaging.
- The PBVR can accommodate our vaccine storage needs without overcrowding stock (including seasonal influenza vaccines).
- Influenza vaccines are separated and clearly labelled into age-appropriate groups that are stored in separate areas of the vaccine refrigerator (do not remove from original packaging).
- All private vaccines are clearly marked and stored separately from the Government funded National Immunisation Program and state-funded vaccines.
- It is best practice to store vaccines in open-weave plastic containers with a solid base. The container should be clearly labelled with the names/s of the vaccines. Space is left between baskets/trays for air circulation.
- Ensure a 'STOP' sticker is clearly displayed on the door.

5 Temperature monitoring and recording

Temperature monitoring and recording of vaccines must be in accordance with the <u>National vaccine storage guidelines - Strive for 5, 3rd edition</u>. Checking and recording the minimum and maximum temperature of the PBVR is an essential element of ensuring that vaccines remain safe and effective.

Twice-daily minimum and maximum temperatures must be manually recorded as a timely alert to any breach in the cold chain in accord with minimum requirements set out in the NVSG. National vaccine storage guidelines 'Strive for 5' – Vaccine fridge temperature chart poster

At a minimum, all PBVR must have a basic data logger (pre-set to 5-minute intervals) and a thermometer to monitor PBVR temperatures continuously.

Temperature and maintenance records should be kept for seven years, in accordance with the General Retention and Disposal Schedule for Administrative Records.

Make/brand of PBVR fridge 1				
Source ^(*) of twice-daily temperature monitoring		□ Data Logger		
		☐ Inbuilt min/max thermometer		
Min/max temperature must be g	raphed twice daily on the NVSG			
chart from ^(*)				
Model				
Size (L) – Internal capacity				
Brand and model of data logger				
Date the date logger's battery wa NOTE: If unable to change the battery,				
life? (i.e. when is it due to be replaced).				
Replacement 'Strive for 5' min/m				
Does the PBVR have a battery backup built into the visual		□ Yes		
temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ No		
*Important notes:				
A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the <u>National Vaccine Storage Guidelines - Strive for 5</u> . The PBVR manufacturer can clarify if your brand/model has this capability.				
	· · · · · · · · · · · · · · · · · · ·	PBVR. Lagging provides the best indication of		
, ,	prevents the alarm from going off unnec			
, ,	Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.			
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is				
in addition to those needed to monitor	each hard-shell cooler.			
Instructions to reset the Inbuilt min/max thermometer				
Steps to download the data				
logger				

Make/brand of PBVR fridge 2		
Source ^(*) of twice-daily temperature monitoring		□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	aphed twice daily on the NVSG	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the National Vaccine Storage Guidelines - Strive for 5. The PBVR manufacturer can clarify if your brand/model has this capability.		
	ases the risk of short-term fluctuations in I prevents the alarm from going off unnece	PBVR. Lagging provides the best indication of essarily.
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 3			
Source ^(*) of twice-daily temperature monitoring		□ Data Logger	
		☐ Inbuilt min/max thermometer	
Min/max temperature must be g	aphed twice daily on the NVSG		
chart from (*)			
Model			
Size (L) – Internal capacity			
Brand and model of data logger			
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.			
Replacement 'Strive for 5' min/max charts are located			
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No	
	*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the National Vaccine Storage Guidelines - Strive for 5. The PBVR manufacturer can clarify if your brand/model has this capability.		
	ases the risk of short-term fluctuations in I prevents the alarm from going off unnece	PBVR. Lagging provides the best indication of essarily.	
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.			
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.			
Instructions to reset the Inbuilt min/max thermometer			
Steps to download the data logger			

Make/brand of PBVR fridge 4		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the NVSG	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
	·	
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual		□ Yes
temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ No
*Important notes:		
A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the <u>National Vaccine Storage Guidelines - Strive for 5</u> . The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data		
logger		

Make/brand of PBVR fridge 5		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the NVSG	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the National Vaccine Storage Guidelines - Strive for 5. The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 6		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	aphed twice daily on the NVSG	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the National Vaccine Storage Guidelines - Strive for 5. The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 7		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the <u>NVSG</u>	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the <u>National Vaccine Storage Guidelines - Strive for 5</u> . The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 8		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the <u>NVSG</u>	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the <u>National Vaccine Storage Guidelines - Strive for 5</u> . The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 9		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the NVSG	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery was last changed: NOTE: If unable to change the battery, what is the data logger's shelf life? (i.e. when is it due to be replaced). Check with the manufacturer.		
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the <u>National Vaccine Storage Guidelines - Strive for 5</u> . The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

Make/brand of PBVR fridge 10		
Source (*) of twice-daily temperate	ure monitoring	□ Data Logger
		☐ Inbuilt min/max thermometer
Min/max temperature must be g	raphed twice daily on the <u>NVSG</u>	
chart from (*)		
Model		
Size (L) – Internal capacity		
Brand and model of data logger		
Date the date logger's battery wa NOTE: If unable to change the battery, we life? (i.e. when is it due to be replaced).	what is the data logger's shelf	
Replacement 'Strive for 5' min/max charts are located		
Does the PBVR have a battery backup built into the visual temperature display? (If yes, ensure the battery is changed in accordance with the manufacturer's specifications)		□ Yes □ No
*Important notes: A lagged temperature source must be used to monitor the temperature of vaccines. This requirement is set out in the National Vaccine Storage Guidelines - Strive for 5. The PBVR manufacturer can clarify if your brand/model has this capability.		
Ambient temperature monitoring increases the risk of short-term fluctuations in PBVR. Lagging provides the best indication of the actual temperature of vaccines and prevents the alarm from going off unnecessarily.		
Information from the data logger must be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored. This is in addition to the twice-daily minimum/maximum recordings.		
A portable minimum/maximum thermometer is required if the PBVR does not have a battery backup in the visual display. This is in addition to those needed to monitor each hard-shell cooler.		
Instructions to reset the Inbuilt min/max thermometer		
Steps to download the data logger		

6 Cold chain breach management

A Cold Chain Breach (CCB) has occurred if vaccine storage temperatures have been outside the recommended range of +2°C and +8°C degrees. This excludes fluctuations up to +12.0°C degrees, lasting no longer than 15 minutes, as may occur when stocktaking or stocking refrigerators.

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

- 1. Immediately isolate the vaccines.
- 2. Inform appropriate personnel within the organisation about the power failure and potential CCB and actions taken.
- Consider the need to begin portable cooler preparation and ice-brick/gel-pack conditioning which can be done by briefly placing the ice-brick/gel-packs in warm water or holding them under running warm tap water until the packs feel soft on the outside.
- 4. 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 solid-walled insulated container/cooler see section 8 of this document or <u>National Vaccine Storage</u> <u>Guidelines Strive for 5 (3rd edition), chapter 9.</u>
- 5. Ensure to place a minimum/maximum thermometer in the PBVR (as it is now non-operational) and in the alternative storage (for ongoing continuous monitoring).
 - NB: Never transfer to a domestic refrigerator.
- 6. Investigate the reason for the power failure and rectify the issue (where possible):

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

Power company:		
Power company phone number:		
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:		
Electricians contact details:		

Important: In the event of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In this instance, use additional bubble wrap to protect the vaccine and monitor the portable cooler closely.

- 7. **Contact QHIP** via email: QHIP-ADMIN@health.qld.gov.au as soon as possible (same or next business day if CCB occurs on a non-business day) using Cold Chain Breach Reporting Form. Provide details on the cause, temperature range and your actions to date. QHIP will notify the PHU of your CCB. A staff member from the PHU will contact the reporting persons and provide recommendations.
- 8. Do not discard any vaccines until advised by the PHU.
- 9. For privately purchased vaccines, contact the manufacturer or supplier for thermostability The Queensland Immunisation Program cannot provide any advice regarding private vaccines.

Actions in the event of a planned or prolonged power outage – out of husiness hours e.g.

SMS/email notification:
Staff members should only attend the practice if safe to do so and must be trained in how to respond to a cold chain breach.
Backup plans in the event of a planned or prolonged power outage (e.g. generator/long-life battery or an agreement with another relevant organisation such as another medical centre):

When the power is returned:

- Record the minimum and maximum temperature of the PBVR and data logger. Depending on the cause of the power failure, the PHU may require evidence of 48 hours of stable temperature monitoring.
- 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. Monitor the PBVR closely (hourly) then as recommended twice daily.

Power outage equipment

Number of solid-walled		Is the cooler capacity	☐ Yes	□No
insulated		adequate to store ALL		
containers/coolers:		vaccines in their		
		original packaging?		
Total storage capacity of		Our clinic has adequate	☐ Yes	□No
all solid-walled insulated		bubble wrap (roll or		
containers/coolers (L):		multiple sheets) /		
		polystyrene chips per		
		cooler:		
Number of portable		Number of frozen ice		
thermometers (1 per		packs/gel packs located		
cooler and 1 per PBVR):		in the clinic:		
Min/max monitoring	☐ Yes ☐ No	Our clinic has ample	□ Yes	□No
charts are available for		empty vaccine boxes		
each solid-walled		available for each		
insulated		portable thermometer:		
container/cooler:				
Date of battery change:		Next battery change is		
Date of battery change.		due:		
Date of slush test:		Next slush test due:		
Details on the backup power supply:				
NB: A cooler is quickly filled when ice packs/gel packs, bubble wrap, loosely packed vaccines, and 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 edition), page 27. A slush test should be conducted after receiving a new thermometer, after changing the battery, and at least every 12 months or sooner if having cold chain problems. Replace the battery of the minimum/maximum thermometers at least every 12 months or sooner if suspecting thermometer issues.

New or recently moved/repaired vaccine refrigerator procedure

If the practice has purchased a new refrigerator or if it has been moved to a new location:

• Ensure that the temperature of the vaccine refrigerator is stable before stocking it with vaccines. To do this, monitor the refrigerator for at <u>least 48 hours</u> before storing vaccines to ensure that temperatures are maintained between +2°C and +8°C. Before using the refrigerator - email 48 hours of temperature monitoring and updated VMP to <u>QHIP-ADMIN@health.qld.gov.au</u> and <u>your local Public Health Unit</u> for approval.

7 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.
- Place ice packs in a sink with warm water to reduce conditioning time if there are time
 constraints in relation to the clinic. This option should **only** be undertaken with caution if
 the above option is not viable to ensure that the ice packs are not over thawed.

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, some industry standards can 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 removes the initial chill factor from the packs.

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

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

Packing a solid-walled insulated container/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.

- 1. Chill the inside of the cooler before use by placing ice packs/gel packs in it for a few hours (Figure 2), then remove the ice packs/gel packs.
- 2. Place polystyrene chips or other suitable insulating material at the bottom of the container (Figure 3). This eliminates 'hot' and 'cold' spots. Packaging such as polystyrene chips is preferable to bubble-wrap because it promotes air circulation. If using bubble-wrap, avoid wrapping the vaccines tightly.
- 3. Place vaccine stock on top of the insulated material (Figure 4).
- 4. Place a minimum/maximum thermometer (or a dual time-temperature indicator if they are used in your state or territory) or data logger in the centre of the vaccine stock (Figure 5).
- 5. Place the thermometer probe in an empty vaccine box (with the product information intact) to protect it from lying directly on ice.
- 6. Surround the vaccines with packing material that allows cold air to circulate.
- 7. Place the conditioned ice packs/gel packs on top of the insulating material (Figure 6), and close and seal the cooler lid. If using a larger cooler, place conditioned ice packs/gel packs around the sides of the cooler and on top. Experiment to find the best combination.
- 8. Ensure that vaccine stock is not in direct contact with the ice packs/gel packs, to minimise the risk of freezing.
- 9. Place the display screen of the minimum/maximum thermometer on the outside of the cooler for easy monitoring and recording of vaccine temperature (Figure 7).
- 10. Commence monitoring before leaving for the session. Monitor the temperature every 15 minutes for the first 2 hours, and then at least hourly throughout the immunisation session, and before administering vaccines (see Appendix 8 'Checklist and temperature chart for mobile or outreach immunisation clinics, or emergency storage of vaccines).

For further information, refer to <u>National Vaccine Storage Guidelines – Strive for 5 (3rd edition)</u>, pq. 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.

8 Mobile or outreach clinics

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

Preparation for the clinic (See	
National Vaccine Storage Guidelines	
- Strive for 5, appendix 7):	
Vaccine monitoring during the	
session	
(See National Vaccine Storage	
Guidelines - Strive for 5, appendix 8):	
Returning remaining vaccines	
to the PBVR	
(See National Vaccine Storage	
Guidelines - Strive for 5, appendix 8):	
0 Manaina	atama eta a al Carallit
y vaccine s	storage self-audit

Immunisation service providers must carry out a vaccine storage self-audit 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 PHU. Temperature and maintenance records must be kept for seven years, in accordance with the General Retention and Disposal Schedule for Administrative Records.

Vaccine storage self-audit conducted on:	
Vaccine storage self-audit due:	

Please ensure that a printed version of this policy is located with the PBVR and that all staff know its location and content.

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

I/we agree to maintain the currency of our Vaccine Management Protocol.



The nominated person responsible for vaccine management:		Principal General Practitioner/Pharmacist or Facility/Nurse Manager:		Practice/Pharmacy/Clinic/Nurse Manager:	
Name:		Name:		Name:	
Signature:	SIGN HERE	Signature:	SIGNHERE	Signature:	SIGN MERE
Date:		Date:		Date:	

Appendix 1

Yellow Fever Vaccination Provider

Australian Government Accredited Yellow Fever Vaccination Centre QLD

The National Guidelines for Yellow Fever Vaccination Centres and Providers | Australian Government Department of Health and Aged Care outlines the procedure and requirements to become an approved Yellow Fever Vaccination Centre. Only approved clinics can give yellow fever vaccinations. They provide vaccination certificates in the form the World Health Organization (WHO) requires.

Current Yellow Fever Vaccination Provider (name)	Yellow Fever Vaccination Course (YFVC) certificate completion date	YFVC certificate provided to PHU ☐ Yes ☐ No	YFVC certificate renewal date (3 years after completion)
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	

To register new Yellow Fever vaccination providers, or to notify change of practice details, the Change/s to Registered Details Yellow Fever Vaccination Centre (YFVC) form within Yellow Fever Information (Registration and qualifications | Queensland Health) must be downloaded, completed and emailed to your relevant public health unit.

Document approval details

Document custodian

Queensland Health Immunisation Program

Approval officer

Dr. Suzi Ossipow Executive Director Communicable Diseases Branch

Approval date: 02/02/2023

Version control

Note: A version control table is useful to keep track of changes that have been made to the document.

Version	Date	Prepared by	Comments / Reason for update
1.0	02/02/2023		The Vaccine Management Protocol has been developed to assist Vaccine Service Providers in developing a VMP that reflects their current
			vaccine storage and management.
1.1	26/07/2023	Laurelle Nelson	Link updates, inclusion of pharmacy information