Graphical user interface, text

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|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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* | |
|  | GCPHU Approval Date: | | | | GCPHU USE ONLY | | | | |  | |
|  |  | | | | | | | | |  | |
| **Vaccine Service Provider (VSP) Number** | | | | | | | | Click to enter text. | | |
| *It is a requirement for VSPs to have an up-to-date Vaccine Management Protocol (VMP) lodged with the Gold Coast Public Health Unit (GCPHU). VSPs without a current VMP will not be eligible to receive vaccine from the Queensland Health Immunisation Program (QHIP).*  ***Please contact GCPHU for any information or advice on (07) 5667 3200 or*** [***GCPHU-CDC@health.qld.gov.au***](mailto:GCPHU-CDC@health.qld.gov.au)***.***  *This Vaccine Management Protocol (VMP) template has been developed based on the National Vaccine Storage Guidelines – Strive for 5 (3rd edition). This template aims to assist Gold Coast VSPs in developing a VMP that reflects their current vaccine storage and management process. Reasons for updating the VMP include (but are not limited to):*   1. *Changes to staff responsible for vaccine management* 2. *Newly purchased purpose-built vaccine refrigerator (PBVR)* 3. *Updates to equipment service dates, staff training (both new and existing) or audit dates* 4. *12 months since last review of the VMP*   *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 aware of its location.*  ***This document needs to be read in conjunction with Strive for 5 (3rd edition) which can be downloaded from:*** [***https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5***](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) | | | | | | | | | | |

Contents

[1. Introduction to vaccine management 2](#_Toc69818389)

[2. Vaccine refrigerator/s 2](#_Toc69818390)

[3. Staff 3](#_Toc69818391)

[4. Vaccine ordering 3](#_Toc69818392)

[5. Receiving vaccines 3](#_Toc69818393)

[6. Temperature monitoring and recording 4](#_Toc69818394)

[7. Cold chain breach management 5](#_Toc69818395)

[8. Preparing a cooler to store vaccines 7](#_Toc69818396)

[9. Mobile or outreach clinics 8](#_Toc69818397)

[10. Vaccine storage self-audit 9](#_Toc69818398)

11. Additional vaccines…………………………………………………………… …………………………………………………….……..…………………………………...9

Appendix 1: Yellow Fever Vaccination Provider…………………………………………………………………………………………………………………………..10

# 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 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.

# Vaccine refrigerator/s

Our practice has the following Purpose-Built Vaccine Refrigerator (PBVR) that is fully compliant with the National Vaccine Storage Guidelines – Strive for 5 (3rd edition):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
| **Purpose Built Vaccine Refrigerator: 1** | | | | |
|  | 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

|  |  |
| --- | --- |
| **Activity** | **Person responsible AND role (job title)** |
| Primary person/role responsible for vaccine management: | Click to enter text. |
| Secondary responsible person/role for vaccine management: | Click to enter text. |
| Recording temperatures at the start of a business day: | Click to enter text. |
| Recording temperatures at the close of a business day: | Click to enter text. |
| Ordering vaccines: | Click to enter text. |
| Receiving vaccines / Checking vaccine expiry dates and rotate stock: | Click to enter text. |
| Orientation for new staff: | Click to enter text. |
| Annual staff education:  Current (within 12 months) certification of training undertaken for all staff responsible for cold chain management available\* | Click to enter text. |
| Annual review of the VMP: | Click to enter text. |
| \*See*–* [*online courses for immunisation service providers*](https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/service-providers/online-courses-for-immunisation-service-providers)*.* Minimum requirement is [Course 4 - Vaccine Management (health.qld.gov.au)](https://www.health.qld.gov.au/__data/assets/pdf_file/0025/1161628/qhip-course-4.pdf) | |

# Vaccine ordering

Government funded vaccines can be ordered from the QHIP via email: [QHIP-ADMIN@health.qld.gov.au](mailto:QHIP-ADMIN@health.qld.gov.au). Download and complete the QHIP [Vaccine Order Form](https://www.health.qld.gov.au/__data/assets/pdf_file/0035/949157/vaccine-order-form.pdf).

Vaccine order must include:

1. Confirmation that vaccines have been stored between +2°C to +8°C.
2. The order date and VSP number.
3. The Practice’s details (name, delivery address, email address, telephone number and fax number).
4. A stocktake identifying the quantity of each vaccine, their expiry dates and quantity required for any additional vaccines.

Advise QHIP if the Practice 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*) | Click to enter text. |

# 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 bullseye and Cold Mark Monitor to ensure that the cold chain has not been broken. If any concerns with cold chain, take a photo of the temperature monitor, complete the [Delivery Issues Reporting form](https://www.health.qld.gov.au/__data/assets/pdf_file/0033/949092/vaccine-delivery-report-form.pdf) and email to [QHIP-ADMIN@health.qld.gov.au](mailto:QHIP-ADMIN@health.qld.gov.au).
* 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 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.
* 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 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 has the capacity to 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 PBVR (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 name/s of the vaccines. Space is left between baskets/trays for air circulation.
* Ensure a ‘STOP’ sticker is clearly displayed on the door.

# Temperature monitoring and recording

Temperature monitoring and recording of vaccines must be in accordance with the [National Vaccine Storage Guidelines – Strive for 5, 3rd edition.](https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf) 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. At a minimum, all PBVR must have a basic data logger (pre-set to 5 minutely intervals) and a thermometer to continuously monitor PBVR temperatures.** ***NOTE:*** *Temperature and maintenance records must be kept for seven years, in accordance with the General Retention and Disposal Schedule for Administrative Records.*

|  |  |  |
| --- | --- | --- |
| **Fridge** **1** | | |
| Brand and model of data logger: | | Click to enter text. |
| 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.* | | Click to enter a date. |
| Frequency the data logger is downloaded and reviewed: | | Click to enter text. |
| **Min/max temperature must be graphed twice daily on the** [**Strive for 5 chart**](https://www.health.gov.au/sites/default/files/documents/2022/07/national-vaccine-storage-guidelines-strive-for-5-vaccine-fridge-temperature-chart-poster-strive-for-5-vaccine-fridge-temperature-chart-poster.pdf) **from** (\*) | | Inbuilt thermometer  Datalogger |
| Replacement Strive for 5 min/max charts are located: | | Click to enter text. |
| 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*](https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf)*. 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.* | | |
|  | Click to enter text. | |
|  | Click to enter text. | |
|  | | |

# 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 PBVR’s.

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

* Immediately isolate the vaccines
* Inform relevant staff members within your organisation about the power outage and potential CCB.
* Consider need to begin portable cooler preparation and ice-brick/gel-pack conditioning (see Section 8 for more information).
* 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 [National Vaccine Storage Guidelines - Strive for 5 (3rd edition), chapter 9.](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5-vaccine-fridge-temperature-chart-poster)

**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. **Never** transfer to a domestic refrigerator, including portable camping refrigerators as these are not suitable for vaccine storage.

* 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).
* Investigate the reason for the power failure and rectify the issue (where possible):

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

|  |  |
| --- | --- |
| Power company: | Click to enter text. |
| Power company 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. |

* **Contact QHIP** via email: [QHIP-ADMIN@health.qld.gov.au](mailto:QHIP-ADMIN@health.qld.gov.au) as soon as possible (i.e. same or next business day) using [Cold Chain Breach Reporting Form](https://www.health.qld.gov.au/__data/assets/pdf_file/0031/949090/cold-chain-breach-report-form.pdf). Provide details on the cause, temperature range and your actions to date. QHIP will notify GCPHU of your CCB and a staff member from the GCPHU will contact the reporting persons to provide recommendations.
* **Do not discard any vaccines until advised by GCPHU.**
* For privately purchased vaccines, contact the manufacturer or supplier for thermostability advice. QHIP cannot provide any advice regarding private vaccines.

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

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

**Backup plans in the event of a** **PBVR malfunction or a planned/prolonged power outage (*e.g. generator/long-life battery or an agreement with another VSP within your organisation*):**

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

**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 GCPHU 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 insulated container/cooler: | Click to enter text. | | Is the cooler capacity adequate to store ALL vaccines in their original packaging? | Yes | No |
| Total storage capacity of all solid-walled insulated container/cooler (L): | Click to enter text. | | Our clinic has adequate bubble wrap (roll or multiple sheets) / polystyrene chips per cooler: | Yes | No |
| Number of portable thermometers  *(1 per cooler and 1 per PBVR):* | Click to enter text. | | Number of frozen ice packs/gel packs located in the clinic: | Click to enter text. | |
| Min/max monitoring charts are available for each solid-walled insulated container/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 edition), page 27](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5). A slush test should be conducted after receiving a new thermometer, after changing a 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 PBVR procedure**

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

* Ensure that the temperature of the PBVR is stable (between +2°C and +8°C) before storing vaccines by monitoring the PBVR for at least 48 hours.
* Prior to transferring vaccines into the PBVR, email 48 hours of temperature monitoring and an updated VMP to [QHIP-ADMIN@health.qld.gov.au](mailto:QHIP-ADMIN@health.qld.gov.au) and [GCPHU-CDC@health.qld.gov.au](mailto:GCPHU-CDC@health.qld.gov.au) for approval.

# 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.
* If there are time restraints, briefly place ice packs under running tap water until the packs feel soft on the outside to reduce conditioning time. ***Note:*** *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**

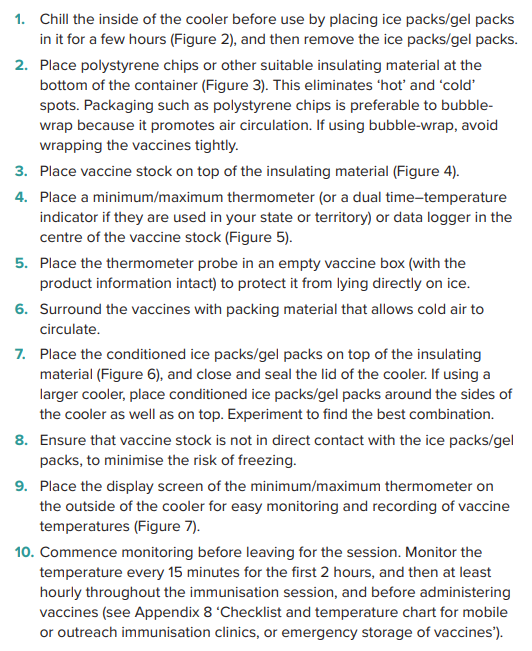
* Usually gel packs will take longer to condition than ice packs. Follow the manufacturer’s instructions for conditioning the gel pack. Although there is no ‘one rule fits all’ approach, there are some industry standards that can be used to guide conditioning if gel packs have been stored in the freezer 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 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.



*For further information, refer to* [*National Vaccine Storage Guidelines – Strive for 5 (3rd edition), pg. 64 - “how to pack a cooler*](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)*”.*

# 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 GCPHU.

***NOTE:*** *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: | Click enter a date. |
| Vaccine storage self-audit due: | Click enter a date. |

# Additional vaccines

**Government funded vaccines**

My practice also offers the following Government funded vaccines (enter YES or NO):

|  |  |  |  |
| --- | --- | --- | --- |
| COVID-19 | Click to enter text. | Japanese Encephalitis Virus | Click to enter text. |
| Rabies/ABLV | Click to enter text. | Mpox | Click to enter text. |

**Approved Vaccination Providers**

|  |  |  |
| --- | --- | --- |
| Yellow Fever Vaccination Provider (through QLD Health) | Yes (see Appendix 1) | No |
| Q Fever Vaccination Provider (through Q Fever Register) | Yes | No |

**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](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)), **in conjunction with the VMP.**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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. |

# 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](https://www.health.gov.au/resources/publications/national-guidelines-for-yellow-fever-vaccination-centres-and-providers) 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](https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/registration-qualifications)) **must** be downloaded, completed and emailed to your relevant public health unit.