

Vaccine Management: Duties and Responsibilities in Vaccination Centres and in Community Settings

Standard Operating Procedure.

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3	Transfer of MMT SOP 0147 ATO / Pharmacy Support Staff Duties v3.1 to PTHB template. Significant update with the introduction of sections for each duty, for clarity.	08/04/2024
4	Section 6.2 Supporting Vaccinators. Inclusion of vaccine specific instruction to ensure that Covid vaccine sits at room temperature for a defined length of time before administration.	18/06/2024
4.1	<ul style="list-style-type: none"> • Amendment to SOP title • Introduction – clarification around staff groups • Responsibilities – minor updates and rewording • Section 6 – Heading -Pharmacy Support Duties changed to Handling Vaccine or similar e.g. vaccine management • Section 6 – reference to pharmacy support removed, replaced with ‘named person’. • Section 6: taking anaphylaxis kits into the community; addition of returning anaphylaxis kits to base • Section 6.3. Refrigerators/Cold Chain -Fridge data logger download- changed from 56 days to weekly. Removal of reference to SD cards. • Section 7 – Training. Clarification of training requirements for different staff groups • Appendix B – title changed from ‘VC Pharmacy Support Duties’ to ‘Weekly vaccine management; weekly duties checklist v1.3’ Reference to SD card removed. Fridge data logger download- changed from 56 days to weekly. 	19/09/2024

Engagement & Consultation

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Item No.	Contents	Page
1.	Introduction	4
2.	Objectives	4
3.	Essential Reading	5
4.	Definitions	5
5.	Role / Responsibility	6
6.	Handling Vaccine	7
7.	Training	13
8.	Monitoring, Compliance, Audit & Review	15
9.	References	15
Appendices		
A	Checking Oxygen Cylinders	16
B	Vaccine Management - Weekly Duties Checklist	17

1 Introduction

Powys Teaching Health Board (PTHB) is committed to the safe and secure handling of vaccines to protect patients and staff.

Nursing staff (registered and unregistered) in vaccination centres (VCs) support this and are integral members of the vaccination team. Staff responsible for the day-to-day management of vaccine are defined as B3 vaccinators. B5/B6 registrants also contribute to vaccine management and act as support for their band 3 colleagues. Both unregistered and registered staff provide a core service in accordance with pharmacy standards and legislation.

VC staff ensure the safe use of vaccines through good vaccine management and governance of the cold chain, and support the provision of a safe, effective, and efficient vaccination service for the residents of Powys.

This SOP clearly outlines the responsibilities and duties required of VC staff within VCs and other community settings to ensure the safe and secure management of vaccine.

It is mandatory for all unregistered staff undertaking pharmacy duties in VCs to be trained and signed off as competent in all aspects of vaccine management and to undertake all other training required for the role e.g. level 2 stock management course (GPhC accredited).

It is mandatory for all registered staff to have a general underpinning knowledge of basic pharmacy legislation and to be able to support their band 3 colleagues, where required in safe management of vaccine (see section 7. Training)

It is mandatory for all staff members to always follow this standard operating procedure.

This process is following compliance with current legislative requirements and good practice guidance.

2. Objective

- To clearly outline the duties required of VC staff to support vaccine management in accordance with pharmacy standards and legislation.

3. Essential Reading

For information to support the requirements of this SOP, the following **must** be read:

- MMP 427 Safe and Secure Management of Refrigerated Medicines / Vaccines
- MMP 429 Safe and Secure Stock Management, Handling & Preparation of Vaccines in PTHB Vaccination Centres and other Community Settings
- MMP 428 Use of Labcold™ Portable Vaccine Carriers
- MMP 432 Use and Management of Helapet Vaccine Porters
- MMP 430 Cleaning / Defrosting PTHB Medicines / Vaccine Refrigerators
- MMP 443 Quarantine, Product Recall and Destruction of Vaccines
- MMP 444 Responding to Pharmaceutical Incidents
- MMP 446 Managing Covid Vaccines During Hot Weather
- MMP 442 Managing Multiple Vaccines at Vaccination Centres
- MMP 447 Vaccination Team/PS Team Stock Management Systems

Vaccine Management SOPs can be accessed here: [Vaccine Management SOPs](#)

4. Definitions

- **PTHB** – Powys Teaching Health Board
- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.
- **Data logger** – an electronic device which allows a detailed analysis of temperature. Data loggers can be used to provide assurance that the cold chain has been maintained and also to provide information about the duration of temperature excursions. Data loggers are frequently placed in medicines refrigerators and in vaccine porters during transportation. .

- **Temperature deviation/excursion** – any incident where the recorded Labcold™ portable vaccine carrier temperature is outside of the recommended range of +2°C to +8°C.
- **Vaccine** – a suspension of attenuated or killed microorganisms (viruses, bacteria or rickettsia) or of antigenic proteins derived from them, administered for prevention, amelioration or treatment of infectious disease.
- **Quarantine**-To separate/isolate affected stock from supply chain which must be clearly labelled with 'Quarantined – do not use' and dated.
- **Supply Chain**- Term used to describe the whole cold chain process from the point of receiving the medication into stock, transport, maintaining the medicines and the point of supplying medication.

5. Role / Responsibilities

5.1 Service Lead

The Service Lead must:

- Ensure all staff read and understand this procedure and that all relevant staff have been appropriately trained.

5.2 Clinical Lead / Senior Nurse

- The clinical lead / senior nurse, in collaboration with the senior pharmacy technician for immunisation / vaccination, therapies and pharmacy stores, is responsible for ensuring that all staff for whom they have responsibility (i.e., anyone who handles vaccines in VCs / community vaccination services) are trained in the operational aspects of vaccine management, have undertaken all other necessary training i.e., cold chain training and have read, understood, and adhere to the standards in this SOP.

5.3 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores (Senior Pharmacy Technician)

- The senior pharmacy technician is responsible for ensuring that staff in VCs are trained to ensure safe management of vaccine.
- The senior pharmacy technician is responsible for arranging regular review to monitor compliance with this SOP, providing vaccine management support, and for ensuring training records are up to date.
- The senior pharmacy technician is responsible for maintaining lines of communication with VC staff to provide support and updates.

5.4 Other Staff

- Unregistered staff supporting the pharmacy role must undertake education and training to meet GPhC standards.
- All staff handling vaccine in VCs, and other community settings are responsible for undertaking cold chain / vaccine storage training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competencies and updating any other training wherever required. Evidence of competencies must be made available on request from the Pharmacy Team.
- All staff are responsible for reading pharmacy related SOPs to support the duties outlined in this SOP (see section 3).

6. Handling Vaccine

Staff who handle vaccine in VCs and any wider community settings must have received training and be competent in vaccine management activities (see section 7). They must:

- Liaise with the VC clinical lead / senior pharmacy technician in relation to all vaccine stock management operational duties and training requirements.
- Refer clinical queries to VC clinical lead or where appropriate, the senior pharmacy technician.

6.1 Vaccine Storage Area

A named person must be assigned to cover the following activities:

- Maintaining the vaccine storage area i.e. keeping the area free from clutter and organizing all consumables/equipment neatly.

- Regular sanitising of the vaccine storage area and equipment i.e. surfaces, high touch areas i.e. fridge handles, vaccine trays.
- Managing the VC anaphylaxis kit (black box) i.e. ensuring that it is locked away in the medicine's cupboard when not in use, ensuring that it is kept in a safe location during vaccination sessions and that staff are aware of the location of the kit.
- Performing regular expiry checks of the contents of the anaphylaxis kit (black box) and informing the senior pharmacy technician in advance of items expiring.
- Managing the small supply of VC anaphylaxis kits for use in community settings (white cartons) e.g. for outreach clinics and ensuring that these kits are not left unattended when taken into the community.
- Ensuring that anaphylaxis kits taken for VCs into community settings are returned to base and locked in the medicine's cupboard at the end of the day.
- Performing regular expiry checks of the contents of the anaphylaxis kits (white cartons) for use in community settings and informing the senior pharmacy technician/B5 pharmacy technician in advance of items expiring.
- Monitoring consumable stocks twice monthly and informing the senior pharmacy technician of low stock levels in a timely manner to ensure that there are no disruptions to the vaccination service.
- Managing Patient Information Leaflets (PILs) and ensuring that the correct PILs are available to hand out to patients for the vaccine in use.
- Performing oxygen cylinder and mask checks (see appendix A)
- Managing vaccination lane folders to ensure that they are present and up to date (check the Table of Contents (TOC) is the most recent version against the TOC in the pharmacy Teams channel)
https://nhs.wales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General?csf=1&web=1&e=H4dqQ3
- Managing vaccine handout toward the end of the day in collaboration with the admin team and the clinical lead to avoid unnecessary waste.
- Preparing vaccine trays in readiness for the next day.
- Ensuring that a new vaccine management checklist (see appendix B) is displayed in the vaccine storage area of the VC at the beginning of each week and ensure that duties assigned to each day are signed off as complete by the team member supporting vaccine management in the vaccine storage area that day. Checklists must be scanned at the end of each week

and saved in the relevant folder located here:

https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/Scanned%20Docs?csf=1&web=1&e=9n52zk Save as e.g. 'week commencing 12.4.24'

- Holding the keys throughout a shift (for fridge and medicines cupboard).
- Supporting training of new staff.
- Responding to pharmaceutical incidents i.e. product re-call, under the supervision of the senior pharmacy technician.

6.2 Supporting Vaccinators

The named person assigned to the vaccine storage area is responsible for:

- Preparing vaccination lanes for vaccinators prior to the start of a vaccination session i.e. ensuring the correct vaccine folder and vaccine signage are present.
- Assembling vaccine trays for vaccinators, ensuring that the correct colour tray is used and that it contains the correct number of consumables for the vaccine in use.
- Ensuring that vaccines are always handled carefully and kept upright (particularly fragile Covid vaccines).
- Ensuring that Covid vaccine removed from the fridge is allowed to sit at room temperature before use as per product SmPC e.g. Spikevax; sit at room temperature for 15 minutes before administration.
- Ensuring that vaccine stock held in the fridge is protected from light (i.e., the vaccine box lid always remains closed).
- Inspecting Covid vaccine vials for particulates by carefully holding up to the light in an upright position, before handing out to vaccinators.
- Reminding vaccinators when vaccine/diluent batch numbers may change mid-session.
- Where necessary, segregating and preparing lanes where different vaccines are being used during a vaccination session. Ensure correct pharmacy folder and signage is in place.
- Preparation of vaccination cards where necessary i.e., stamp with location, vaccine name, batch number and date. NB. Prepare only required number of vaccination cards per vaccine batch to avoid waste i.e., if changing batches during a shift. If dating cards, prepare only enough for the present shift. This will avoid waste.

6.3 Refrigerators / Cold Chain

The named person assigned to the vaccine storage area is responsible for:

- Monitoring fridge temperatures and recording on the Welsh Immunisation System (WIS), twice daily.
- Ensuring that vaccine fridges are locked when not in use.
- The swift transfer of vaccine deliveries from +2°C - +8°C to the VC refrigerator to ensure maintenance of the cold chain.
- Ensuring that when fridges are in use, that the fridge door is opened for the absolute minimum amount of time.
- Ensuring that the fridges are not overloaded with stock (NB. 50% capacity), to allow the air to circulate freely.
- Responding to and reporting temperature excursions immediately to the clinical lead and the senior technician. If the senior technician is unavailable, contact the B5 pharmacy stores technician or Medicines Management Team immediately, for advice: info.medicinesmanagement.powys@wales.nhs.uk
- Following the procedure for quarantining stock.
- Management of data loggers i.e. downloading data and re-setting after use. Fridge data loggers should be downloaded every week, or sooner if a fridge temperature excursion occurs, and vaccine porter data loggers after every use.
- Analysis of data logger download and saving in the relevant file [Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#).
- Ensuring that there are spare replacement batteries in the VC for the refrigerator.
- Responding to fridge alarms quickly and efficiently.
- Checking that fridges are being used within their calibration period (date of next calibration is located on a sticker on the outside of the fridge).
- Informing the MMT immediately if the fridge does not seem to be operating efficiently: info.medicinesmanagement.powys@wales.nhs.uk
- Cleaning vaccine refrigerators (defrosting where necessary).

6.4 Stock

The named person assigned to the vaccine storage area is responsible for:

- Monitoring stock levels and recording on WIS twice daily.

- Reporting stock levels, batch numbers and expiry dates to senior technician for immunisation/vaccination once weekly.
- Receipting stock onto WIS.
- Ensuring stock is rotated so that shortest dated stock is at the front of the fridge to be used first.
- Monitoring vaccine expiry dates to ensure that waste is avoided.
- Segregating different vaccines on separate shelves in the fridge to avoid errors in choosing the wrong vaccine.
- Managing stock returned from community settings i.e., care homes/outreach, to ensure that the cold chain can be assured before returning to stock (i.e. analyse the data logger download and save in the relevant file [Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#)). Inform the senior technician immediately, if any temperature excursions (for any length of time) are evident from the data download.
- Where cold chain maintenance can be assured (e.g. from data logger download), ensuring boxes of vaccine returned from community settings are clearly marked with a small cross and the date. This must be done every time a box is returned to stock. NB. This applies to Influenza and MMR vaccine only.
- Entering stock wastage onto WIS.
- Using stock management systems for vaccines not supported by WIS i.e. MMR vaccine.
- Managing vaccine orders for community settings i.e. for care homes, outreach. Raise a reference number and complete the VC Order Processing Spreadsheet located in the Pharmacy Teams channel
https://nhs.wales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/VC%20ORDER%20PROCESSING?csf=1&web=1&e=T5f0Yw

6.5 Vaccine Porters – Helapet

The named person assigned to the vaccine storage area is responsible for:

- Managing VC Helapet vaccine porters and cool packs i.e. ensuring excess VC Helapet vaccine porters/cool packs are returned to pharmacy stores and that VC Helapet vaccine porters and cool packs are cleaned after each use.
- Ensuring that cool packs are cooled in the fridge for 24 hours before re-use and the relevant paperwork is used to indicate when the cool packs will be next ready for use.

- Ensuring Helapet vaccine porters are loaded correctly i.e. the correct number and size of cool packs are chosen for the vaccine porter in use and that the vaccine porter is lined with bubble wrap prior to filling with vaccine.
- Ensuring a data logger has been reset and is placed in the Helapet vaccine porter with the vaccine before it leaves the VC.
- Management of data loggers i.e. downloading data and re-setting after use. Vaccine porter data loggers must be downloaded after every use, analysed for cold chain assurance and the data downloaded and saved in the relevant file.
[Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#)
- Inform the senior technician immediately, if any temperature excursions (for any length of time) are evident from the data download.

6.6 VC Vaccine Porters/cool packs stock levels

The named person assigned to the vaccine storage area is responsible for:

- Maintaining 2 large vaccine porters and 24 large cool packs in the VC in case of emergencies (i.e., power failure). Each centre should also keep one medium vaccine porter and 28 small cool packs (for ad hoc use in the community) and one small vaccine porter and 12 small cool packs (for ad hoc use in the community). In total:
 - 2 large Helapet vaccine porters
 - 1 medium Helapet vaccine porter
 - 1 small Helapet vaccine porter
 - 24 large cool packs
 - 40 small cool packs
 N.B. These quantities can be increased during busier periods or decreased during quieter periods.
- Do not stack cool packs more than 3 high in the refrigerator.

6.7 Vaccine Porters - Labcold™

The named person assigned to the vaccine storage area is responsible for:

- Managing Labcold™ Portable Vaccine Carriers i.e. ensuring they are plugged in, and that the temperature has stabilised between +2°C - +8°C before use.

- Ensuring a data logger has been reset and is placed inside the Labcold™ Portable Vaccine Carrier with the vaccine before it leaves the VC.
- Management of data loggers i.e. downloading data and re-setting after use. Vaccine porter data loggers must be downloaded after every use, analysed for cold chain assurance and the data downloaded and saved in the relevant file.
[Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#)
- Inform the senior technician immediately, if any temperature excursions (for any length of time) are evident from the data download.
- Ensuring that Labcold™ Portable Vaccine Carriers are cleaned (with Clenil wipes) after use and are stored safely and securely to avoid damage to the unit.

7. Training

All staff handling vaccine within VCs/Community Settings must be trained and competent to do so.

Unregistered staff supporting the pharmacy role must undertake education and training to meet GPhC standards i.e. Level 2 qualification in Stock Management.

Unregistered staff - The following training must be completed:

- New starters must work alongside a trained and competent member of the VC team for a period of time to familiarise themselves with the principles of vaccine management and associated practical duties, before competencies can be signed off. This time may vary between individuals, according to experience.
- Following adequate training and where the individual feels confident and competent to undertake the practical duties associated with vaccine management with minimum support, competencies can be signed off; either by trained and competent VC pharmacy support staff e.g. GPhC accredited staff member or by the senior technician / pharmacy technician.
- Competency sign off sheets can be accessed here:
[https://nhswales365.sharepoint.com/:f:/r/sites/POW MVCPharmacyTeam/Shared%20Documents/General/Signed%20competency%20checklists?csf=1&web=1&e=Ds6roW](https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/Signed%20competency%20checklists?csf=1&web=1&e=Ds6roW)
- The signed competency sheet must be forwarded to Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk

Registrants

In line with the National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners, registrants undertake training in relation to the Legal issues and the Storage and handling of vaccination. These are mandatory modules within the NHS Wales Immunisation Programme which are included within the local Immunisation and Vaccination service training matrix.

Registrants are responsible for identifying their own training needs and will be supported by GPhC accredited B3 vaccinators, B5 pharmacy technician and the senior pharmacy technician:

- Registrants must have a general underpinning knowledge of basic pharmacy legislation and to be able to support their band 3 colleagues, where required in safe management of vaccine. The senior technician can facilitate this training.
- Registrants must be proficient in the practical elements necessary to ensure the safe and secure management of vaccine in VCs and in community settings:
 - Taking and recording fridge temperatures
 - Using data loggers
 - Use of WIS e.g. fridge/stock monitoring
 - Use of vaccine porters
 - Maintaining the local stock management system
 - Good understanding of stock management e.g. how to store vaccine correctly, stock rotation/expiry date checking
 - Managing waste

All unregistered and registered staff are responsible for ensuring that training records relating to vaccine management are up to date and signed for e.g., Reading SOPs including updates, data logger training.

All staff must also be up to date with cold chain and vaccine storage training which can be accessed via ESR:

[070 Cold Chain Training –The safe and secure management of refrigerated medicine](#)

[000 Vaccine Storage](#)

All staff handling vaccine in VCs and community settings must be familiar with Good Distribution Practice (GDP). GDP training is

undertaken individually in the form of a PowerPoint presentation and is certificated 'in-house'. For information on how to access this training contact Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk

All staff handling vaccine must be familiar with, and have access to:

- The PTHB Management of Refrigerated Medicines SharePoint page:
[Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#). This SharePoint page can be accessed by all PTHB staff involved in the management of the cold chain. All documentation referred to in PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines / Vaccines, can be accessed via this folder and via links throughout the SOP.
- VC Pharmacy Teams channel. This channel is for VC staff only and contains documentation/spreadsheets etc., specific to the role of VC pharmacy support staff. Access here:
https://nhs.wales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General?csf=1&web=1&e=RDJOWD

8. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits in vaccination centres.

This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

9. References

PTHB Vaccination Centre SOPs [Vaccine Management SOPs](#)

Appendix A Checking Oxygen Cylinders

Check the expiry date on the batch label. If expired or close to the expiry date report to Vaccination Centre (VC) clinical lead to order a replacement.



Check the contents gauge to ensure that there is sufficient gas (see below). The needle must be within the green zone. If the needle is in the red zone report to the VC clinical lead to order a replacement.

NB. Do not wait until the needle is in the red zone before requesting a replacement.



