Safe & Secure Stock Management and Handling of Vaccines in Powys Teaching Health Board Vaccination Centres and Other Community Settings

Standard Operating Procedure.

Document Reference No:	PTHB / MMP 429	
Version No:	8	
Issue Date:	April 2026	
Review Date:	April 2029	
Author:	Senior Pharmacy Technician	
Document Owner:	Chief Pharmacist	
Accountable Executive:	Medical Director	
Approved By:	PTHB Vaccination and Immunisation Operational Development Group	
Approval Date:	16/04/2026	
Document Type:	Standard Operating Procedure	Non-clinical
Scope:	PTHB	

The latest approved version of this document is online.
If the review date has passed, please contact the Author for advice.

Version Control:

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue. • This SOP incorporates the following retired SOPs: **SOP 0154** Vaccine Stock Management at Vaccination Centres, Autumn/Winter 2023/24 **SOP 0130** Receipt of Covid Vaccine on WIS, **SOP 0131** Managing Vaccine Consumables, **SOP 0134** Vaccine Fridge Monitoring & Excursions in Pharmacy Stores and Vaccination Centres, **SOP 0153** Safe and Secure Stock Management, Handling and Preparation of Childhood Vaccines in PTHB VCs • Inclusion of information regarding Influenza vaccine • The term "nucleoside modified" removed from all strengths of Pfizer Comirnaty® Omicron XBB.1.5▼ as per the regulatory update from Pfizer.	08/04/2024
2	Updates: • Removal of references to pharmacy support, switched to vaccine management and/or member of staff on duty to support vaccine handout. • Removal of section 11 – Issuing Vaccine to District Nurses. • Addition of Abrysvo powder and solvent for solution for injection (RSV Vaccine) • Inclusion of vaccine management responsibilities for registrants • Pharmacy Keys & Security: Inclusion of paragraph to remind staff that the fridge must be locked when the pharmacy area is left unattended. • Receipt of vaccine: RSV included for management via WIS • Stock checks: RSV included for management via WIS. • Data logger download, changed from 56 days to once a week.	19/09/2024

	• Removal of reference to refrigerator SD card download • WIS: Addition of RSV vaccine when receiving vaccine into stock. • Handling vaccine at vaccination centres: Addition: Use blue trays for RSV vaccine • Flu walkabouts: clear instructions to return unused vaccine to pharmacy stores, provided that cold chain maintenance can be demonstrated. • Covid vaccines updated: new variant (JN.1) Covid vaccines added including images of vials. • Addition of Abryvso administration instructions • Removal of Nuvaxovid vaccine administration instructions • Removal of Bimervax vaccine administration instructions	
3	Updates: Section 7.1. Receipt of vaccine. • Addition of identification of Abrysvo (RSV vaccine) in vaccination centres as specific to the adult vaccination programme. Labeling vaccine boxes 'ADULT'	28/01/2025
4	Updates: • Change to title (removal of 'preparation of vaccines) • Removal of consumable stock check requirement • Removal of Section 11. Covid Vaccines & removal of Section 12. Other Vaccines (as COVID-19 vaccines in use in the UK now all have Marketing Authorisations, therefore detailed administration instructions and product characteristics can be found in other documentation e.g., SmPC/PGD) • Removal of appendices relating to administration instructions of vaccines. • Addition Section 10 – Using Multiple Vaccines During a Vaccination Clinic • Addition Section 12 – Managing Covid-19 Vaccine During Hot Weather	09/06/2025

	• Addition – Appendix B – Ambient Temperature Monitoring Log	
5	Updates: • Addition of section 13. Products Requiring Ambient Temperature Storage • Reminder added for appropriately naming data logger downloads when saving. • Addition of use of monitoring forms for vaccine porters. • Addition of appendices – monitoring forms for vaccine porters	01/09/2025
6	Updates: • Section 14. Transport of vaccine, 14.1; Addition of bullet point to plug portable vaccine carriers into the vehicle power source and safely secure unit. Reference to MMP 428 added. • Section 18. Punctured vials of Covid Vaccine; example added for clarification of when it may be appropriate to transport punctured Covid vials between sites.	12/11/2025
7	Updates: • Section 8.4 Stock Management and Fridge Monitoring During Vaccination Sessions – WIS: removal of reference to a limited period (e.g., 24 hours) to edit incorrect WIS entries. Addition of ability to edit WIS entries at any time and to report edits to the Pharmacy Store team for monitoring purposes. • 8.5 Welsh Immunisation System (WIS) – clarity around entering deliveries on WIS from external suppliers but not from internal vaccine transfers. • Section 9 Handling Vaccine in Vaccination Centres and in Community Settings - update regarding number of vaccines that can be handed out to vaccinators e.g. exceptions to the rule.	16/04/2026
8	• Updates: Removal of reference to the nurse administering Covid vaccine	24/04/2026

	doses being solely responsible for entering the batch number onto WIS.	

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
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Circulated to the following for Consultation

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19/09/2024	Vaccination Programme Operational Development Group for update approval
04/06/2024	Head of Service, Community Pharmacy Service
28/08/2025	PTHB Vaccination and Immunisation Operational Development Group
08/04/2026	Vaccination Programme Operational Development Group for update approval

1 Introduction

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

It is mandatory for all staff members involved in managing vaccines to always follow this standard operating procedure.

The efficacy and safety of vaccines requiring controlled low temperature storage ultimately depends on the safe handling of vaccine and maintenance of temperatures within the manufacturers' recommended range, typically +2°C to +8°C. If the handling and storage recommendations are not followed, manufacturers can disclaim responsibility for any apparent failure of the product as they will no longer be within the terms of the marketing authorisation (product license).

Vaccines are biological substances that may lose their effectiveness rapidly if they become too hot or too cold at any time. Inadequate temperature control during storage and transport of vaccines or other fridge line pharmaceuticals can reduce the efficacy of the product. This is particularly important during transport and storage of vaccine as failure to provide the correct storage conditions can result in compromised attainment of a satisfactory level of immunity.

Vaccine failures caused by the administration of a reduced potency vaccine can affect a large number of people causing risk to patients, embarrassment to the organisation, expense and possible liability. Patient confidence in vaccine products and the vaccination process are diminished if repeat vaccination is required[1].

In addition to the safe handling of vaccines and maintenance of storage temperatures, stock management Excel spreadsheets must be maintained to satisfy pharmaceutical regulatory requirements.

2. Objective

- To ensure suitably trained and competent vaccination centre (VC) staff safely and securely receipt, store, manage and where necessary distribute vaccine stocks for administration to patients at Powys Teaching Health Board (PTHB) Vaccination Centres (VCs), outreach clinics and other community settings

[1] 7th revision vaccine handling and storage advice Sept 17.pdf

e.g. care homes, in accordance with pharmacy standards and legislation.

- To ensure that individuals who store, handle or administer vaccines are aware of the requirements to store the vaccine correctly and in line with the recommendations set out in Chapter 3 of the Green book Green_Book_Chapter_3_v3_0W.pdf (publishing.service.gov.uk). This will ensure the integrity of vaccine products and reduce the risk of compromising the quality, efficiency, and safety of the vaccination programme, whilst improving the service for patients.
- To clearly define record keeping requirements in line with pharmacy standards, legislation and Vaccination Programme Wales (VPW) expectations.
- To ensure that staff are aware of fridge / medicine cupboard key security arrangements.
- To ensure that staff understand the importance of fridge temperature monitoring and are competent to undertake this task.
- To understand the procedure for taking appropriate corrective and timely action in the event of a temperature excursion outside of the cold chain range of +2°C to +8°C.
- To ensure that staff understand the principles of stock rotation.
- To ensure that staff understand the importance of expiry date checks.
- To ensure that staff understand the principles around the safe handling of vaccines in accordance with the manufacturers Summary of Product Characteristics (SmPCs)

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 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 439 Roles, Responsibilities and Training – Vaccine Management in Vaccination Centres and in Community Settings
- MMP 443 Quarantine, Product Recall and Destruction of Vaccines
- MMP 444 Responding to Pharmaceutical Incidents

- MMP 447 Vaccination Team/Pharmacy Store Team Stock Management – Record Keeping

All SOPs can be accessed via the vaccine management SOP folder located in each vaccination centre and via the Medicines Management website Policies, Procedures, Protocols, SOPs and Guidelines - Powys Teaching Health Board

Summary of Product Characteristics (SmPCs) and Information on Patient Information Leaflet (PILs) updates can be accessed here: Home - electronic medicines compendium (emc)

4. Definitions

- **ATO** – Assistant Technical Officer
- **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.
- **HCSW** – Health Care Support Worker
- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **Medicine** – a substance used for treating, preventing or diagnosing disease, for contraception, inducing anaesthesia or modifying normal physiological function.
- **PIL** – Patient Information Leaflet
- **PTHB** – Powys Teaching Health Board
- **Quarantine**-To separate/isolate affected stock from supply chain which must be clearly labelled with 'Quarantined – do not use' and dated.

- **SmPC** – Summary of Product Characteristics

- **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.

- **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.

- **VPW** – Vaccination Programme Wales

5. Role / Responsibilities

5.1 Senior Pharmacy Technician, Vaccination/Immunisation & Pharmacy Stores (Senior Pharmacy Technician)

The senior pharmacy technician is responsible for:

- Ensuring that this SOP is kept up to date and informing staff of any changes.
- Ensuring clinical governance relating to vaccine stock management is maintained.
- Ensuring that VC staff are trained and competent to perform the duties required of them and that training meets the requirements of the General Pharmaceutical Council (GPhC).
- Ensuring that all VC staff have received relevant training relating to vaccine stock management (see section 5) and where applicable, are signed off as competent to undertake their duties with minimum supervision (e.g., Healthcare Support Worker (HCSW) Immunisers).
- Providing any training sessions required to ensure that all staff understand the principles of robust vaccine stock management, according to pharmaceutical standards and legislation.
- Maintaining contact with VC staff and to oversee management of operational vaccine management duties.

	• Ensure all staff are aware of actions to take and who to contact if there are any issues with the refrigerator / cold chain. • To make sure that staff are aware that any vaccines subject to a breach in the cold chain are quarantined until expert advice is sought from the Medicines Management Team. • Annual vaccine management audits.
	5.2 Service Lead **Senior Clinical Lead Nurse, Vaccination Service must:** • Ensure all staff read and understand this procedure. **5.3 Clinical Nurse Leads, Vaccination Service** • The clinical leads in collaboration with the senior pharmacy technician, are responsible for ensuring that all appropriate staff for whom they have responsibility (e.g., anyone who has any involvement in vaccine management) have undertaken all necessary training (see section 6) and have read, understood, and adhere to the standards in this SOP. • The clinical leads are responsible for ensuring that the senior pharmacy technician is provided with the VC vaccine management rota in advance, monthly. **5.4 Other Staff (e.g., registrants and HCSW Immunisers)** • With support from the senior pharmacy technician/pharmacy stores pharmacy technician, unregistered staff (HCSW Immunisers) must undertake education and training to meet GPhC standards to be able to safely manage vaccines. • All staff (registered and HCSW Immunisers) 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. • All staff are responsible for reading pharmacy related SOPs to support the duties outlined in this SOP. • All staff are responsible for signing and dating the SOP log attached to each SOP when read (see section 3). • VC staff are responsible for maintaining accurate stock management records e.g. WIS and stock management

Excel spreadsheets (childhood/teenage vaccine logs / vaccine delivery logs).

- VC staff are responsible for reporting vaccines subject to a breach in the cold chain to the senior clinical lead/lead nurse/senior pharmacy technician.
- VC staff are responsible for quarantining vaccines subject to a temperature breach in alternative cold storage until expert advice is sought from the Medicines Management Team.
- All staff must have an understanding of the importance of good vaccine management and Good Distribution Practice (GDP) and have undertaken the relevant training.
- All staff must be aware of the importance and the need to quickly and efficiently transfer vaccine deliveries to the refrigerator as soon as they arrive on site.
- Prior to handing out vaccine, it is the responsibility of staff to make sure that the vaccine remains within the manufacturer's recommendations for storage.

Tasks outlined in this SOP must be clearly assigned to named individuals for each vaccination session.

This SOP should be read in conjunction with all VC vaccine management SOPs.

All SOPs can be accessed via the vaccine management SOP folder located in each vaccination centre.

This SOP links with MMP 439 Vaccine Management: Duties & Responsibilities in Vaccination Centres and Community Settings

6. Training

All staff involved with any aspect of cold chain management are responsible for undertaking training and maintaining competencies. Staff can access cold chain and vaccine storage training via ESR:

070 Cold Chain Training –The safe and secure management of refrigerated medicine

000 Vaccine Storage

These must be updated annually on ESR.

HCSW Immunisers (unregistered staff) supporting vaccine management must undertake education and training to meet GPhC standards, e.g. Level 2 qualification in Stock Management.

New HCSW Immunisers must receive adequate training in operational duties before being signed off as competent. Competency check lists can be found here:
Competency Checklists Vaccine Management

All VC staff involved with transportation of medicines/vaccines must be familiar with Good Distribution Practice (GDP). GDP training is available for PTHB staff. GDP training is undertaken individually in the form of a PowerPoint presentation and is certificated 'in-house'. A GDP training refresher must be completed annually. For information on how to access this training contact Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk

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 the senior pharmacy technician / pharmacy stores pharmacy technician.

For further information on roles, responsibilities and training for VC staff, please refer to MMP 439 Roles, Responsibilities and Training – Vaccine Management in Vaccination Centres and in Community Settings

7. Keys and Security

7.1 Overview

Keys to the vaccine refrigerators and medicines cupboard must be kept in a secure location and access made available to authorised personnel only. These are:

- Medicines Management Pharmacy Technicians, Assistant Technical Officers (ATOs) and Pharmacists
- Senior Clinical Lead (and deputy) and Vaccination Centre Lead Nurses.

- Vaccination Centre Registrants and HCSW Immunisers.

7.2 Refrigerator/Medicines Cupboard Keys

- Keys must be locked in a key safe when the VC is closed.
- Only those staff competent in vaccine management should have access to the key code and key safe.
- Keys must be held by a named member of staff supporting vaccine management for the entire vaccination session or handed over to another authorised member of staff, where shifts may be split, or where cover is required for breaks.
- When the vaccine storage area is vacated e.g., lunchtime/breaks, key holders on duty must ensure that the fridge and medicine cupboard are locked, including securing the adrenaline in the medicine's cupboard.
- Where the vaccine storage area is unattended, the fridge door must be locked e.g., when the named member of staff supporting vaccine management is called away to vaccinate.
- The named member of staff supporting vaccine management must ensure that the fridge and medicines cupboard keys are returned to the dedicated key safe at the end of the day.
- **KEYS MUST NOT BE TAKEN OFF SITE**

8. Receipt of vaccine, Fridge Temperature Monitoring and Storage of Vaccine

8.1 Receipt of Vaccine

Vaccine must be maintained at a temperature of between +2ºC to +8ºC for the entirety of the supply chain e.g., from product manufacture to administration to a patient.

- All vaccine will be delivered to VCs at a prearranged date and (where known, time) at a temperature of between +2ºC to +8ºC.
- Vaccine must be transferred immediately from +2ºC to +8ºC conditions to the VC refrigerator in order to maintain the cold chain. Ensure that the fridge temperature has been maintained between +2ºC to +8ºC (see section 8.4).
- Stock must be checked against the delivery note for accuracy (e.g., check that the vaccine type, brand, quantity, batch number and expiry match that of the delivery note).
- A signature, date and time must be recorded on the delivery note to acknowledge receipt of the vaccine delivery (this will be the VC copy, which must be scanned onto the system). The

delivery driver may also request a further signature via a handheld device.

- Ensure the product received is in good condition e.g., intact, packs are not crushed.
- Stock that has not been stored correctly, e.g., if the cold chain has not been maintained during delivery, should be rejected, and returned to the driver. Contact the senior pharmacy technician immediately for advice.
- On receipt, vaccines must be unpacked from the outer cardboard box or vaccine porter but must be kept in the original packaging and placed into the designated fridge immediately and not left at room temperature.
- When putting stock away ensure that stock is rotated e.g., shorter dated stock to the front of the fridge to be used first (see section 8.2)
- Receipt Covid/Flu/RSV vaccine on the Welsh Immunisation System (WIS), where available. All other vaccine should be receipted via the stock management Excel spreadsheet (see section 8.5).
- RSV vaccines administered in vaccination centres are for the adult vaccination programme only.
- Delivery notes must be scanned and saved in the relevant VC folder, located here: https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/Scanned%20Docs?csf=1&web=1&e=PN4hUH
- Covid vaccine consumables will be delivered with the vaccine e.g., syringes, Patient Information Leaflets (PILs), ensure that these are safely stored.

8.2 Stock Rotation and Storage

- Rotate stock so that the oldest stock (shortest expiry) is at the front of the fridge to be used first. When checking the expiry date, in most cases the vaccine will expire on the last day of the month. i.e. 05/24 means the vaccine expires at 23:59 on the last day of May. There are some exceptions to this as vaccines such as the nasal influenza and COVID-19 vaccines expire on a specific date in the month.
- Excessive stockpiling of vaccines must be avoided in case of fridge failure and to reduce potential waste.
- Ensure that different vaccines are separated in the fridge e.g., on different shelves.
- Refrigerators should not be over-filled. Sufficient space must be maintained within the fridge to permit adequate air circulation.

- Cool packs should be stored in a separate fridge from the vaccine.
- Food, drinks and clinical specimens must never be stored in the same refrigerator as medicinal products.
- Fridges must be cleaned regularly and defrosted where necessary - see essential reading, section 3.

8.3 Stock Checks

The named person assigned to the vaccine management during a vaccination clinic is responsible for checking stock quantities:

Prior to the start of a vaccination session - record current stock levels on WIS e.g., Covid/Flu/RSV vaccine (also see section 8.5) or the stock management Excel spreadsheet e.g., MMR vaccine)

- At the end of a vaccination session - complete as above.
- Provide a full stock check once weekly (including batch numbers and expiry dates) to the senior pharmacy technician, to inform VPW.
  NB. When undertaking stock checks, aim to keep the fridge door open to an absolute minimum, for the shortest possible time. If the fridge temperature begins to rise, then close the fridge door, and wait until the temperature becomes stable again before continuing. **NB. When performing a stock check, be aware that some boxes of vaccines may be part boxes.** Part boxes must be marked with a cross on the lid to indicate that they have been opened and that vials have been removed.
- Where possible ask a colleague to perform a second check (e.g., registrant / HCSW Immuniser) before submitting the final stock count (especially at times of high-volume stock).

8.4 Stock Management and Fridge Monitoring During Vaccination Sessions

- Stock management and monitoring of vaccines during vaccination sessions are the responsibility of the named member of staff on duty for vaccine management.
- Vaccines must be stored safely and securely in a refrigerator between +2°C to +8°C to ensure that they are not compromised, and efficacy is maintained.
- The temperature within the vaccine refrigerator must be monitored regularly by an appropriately trained individual who is aware of the action to take if a fridge temperature excursion occurs.

- All static fridges in the VCs must contain a data logger, and the data downloaded **once weekly** (unless a fridge temperature excursion occurs before then), then reset – a reminder must be added to the hardback VC diary to ensure that this happens regularly. The downloaded data must be saved in the relevant Management of Refrigerated Medicines/Vaccines SharePoint folder Medicines Management - Management of Refrigerated Medicines _ Vaccines - All Documents (sharepoint.com)and named appropriately e.g., 'CH Vaccine fridge 02/05/2025'.
- Fridge temperature readings must be recorded on the Welsh Immunisation System (WIS) twice daily (am and pm). The maximum, minimum and actual temperature must be recorded, then the fridge temperature must be reset.
- Stock checks must be entered onto WIS twice daily (am and pm) and following transfer of vaccine into the community and on receipt of vaccine orders/return of vaccine from community settings to the VC.
- Care must be taken entering data onto WIS, particularly stock levels. It is good practice for a second stock check to be performed by a colleague (e.g., registrant / HCSW Immuniser) before entering the stock count onto WIS, especially during times of high-volume stock. Incorrect stock counts can affect vaccine orders (e.g., insufficient or too much vaccine may be ordered based on current WIS stock levels), which in turn may potentially impact on the smooth running of the vaccination service and/or produce waste.
- WIS entry errors are editable. Edited WIS entries will be monitored and must be reported to the Pharmacy Store team.
- A stock monitoring sheet may be used during the vaccination session to keep a running total of the number of vials used and to keep a record of ad hoc fridge temperature monitoring throughout the vaccination session (see Appendix A). There is no requirement to keep this record at the end of the day, but it is useful to file copies for a week at a time, in case of stock discrepancies.
- When issuing vaccine from the refrigerator, ensure that the fridge door is opened for the minimum amount of time to avoid warm air entering and compromising the temperature.
- In the event of a fridge failure in the vaccination centre all vaccine must be transferred into vaccine porters to maintain the cold chain. Both VCs have sufficient emergency vaccine porters and cool packs on site to support this. NB. Storage of vaccines in a vaccine porter during vaccination sessions in vaccination centres should only be necessary if a fridge failure has occurred. A data logger must be placed into the vaccine porter to record the temperature. Immediate advice should be

sought from the VC clinical lead nurse & senior pharmacy technician if a fridge failure occurs.

NB. Vaccine porters may be used to store vaccine during vaccination clinics in a community setting e.g. at outreach clinics. Data loggers must be used.

Refer to PTHB SOP MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines for further guidance on monitoring refrigerators and for the detailed instructions for managing refrigerator temperature excursions

8.5 Welsh Immunisation System (WIS)

- Currently (as of March 2026) Covid, Flu and RSV Vaccines delivered to VCs from external suppliers e.g. ImmForm, IP5 must be recorded as a delivery on WIS and must immediately be added to stock on WIS. NB. Only vaccine delivered directly from an external supplier must be recorded as a delivery on WIS
- Deliveries for all other vaccine (e.g., MMR) including stock checks and waste reporting, must be recorded via the stock management Excel spreadsheets (these can be found on the VC Teams channel https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/CHILDHOOD%20IMMS?csf=1&web=1&e=3aG7CE) NB. National vaccine monitoring systems are being continually updated, therefore more vaccines will be added to the system over time.
- Where vaccine is transferred between sites within the Health Board, for example, as an internal delivery from the Pharmacy Store to Vaccination Centres, then the Pharmacy Store team will add the vaccine movement as a transfer on WIS. On receipt of the stock at the Vaccination Centre, it must not be added to the delivery section of WIS. This is because it has already been receipted into the organisation (e.g. on WIS) by the Pharmacy Store Team. The stock received must however be added to the stock check on WIS, immediately on arrival.
- Fridge temperatures must be recorded twice daily on WIS.
- Twice daily stock checks must be recorded on WIS.
- Waste must be recorded on WIS.
- Where appropriate, vaccine transfer must be recorded on WIS (see section 11).

9. Handling Vaccine at Vaccination Centres & Community Settings

Vaccines are Prescription Only Medicines (POMs), and therefore, the fridge should always be locked when not in use or kept in a locked room. Vaccines should never be left unattended once removed from the fridge.

- The correct coloured vaccine/consumable trays must be selected to correspond with the intended vaccine in use for the vaccination session e.g., Adult Covid vaccine / RSV vaccine – **blue trays**, Childrens Covid vaccine - **orange trays**, other childhood immunisations – **green trays**, Influenza vaccine – **red trays**.
- Only ONE vaccine must be handed out to a vaccinator and be present in a vaccination lane at any one time. The only exception to this is where vaccines are being co-administered e.g., Covid and Flu, Covid and RSV, or where planned vaccination catch up programmes are operating alongside another vaccination programme In this case it is acceptable for different vaccines to be present in the vaccination lane, but care must be taken (see section 10).
- For Covid vaccine, the corresponding number of consumables (and diluent, where required) must be placed in the tray according to the vaccine being used and the number of doses contained in the vial e.g., Spikevax multidose vial (5 doses); 5 syringes, 6 swabs, 5 vaccination cards.
- All vaccinees must be provided with a Patient Information Leaflet.
- Vaccines that have been removed from the refrigerator or vaccine porter that have expired (e.g., that have left the cold chain), cannot be re-used or returned and must be destroyed of according to PTHB disposal of waste regulations. Waste doses must be recorded on WIS.
- The named member of staff supporting vaccine management must flag up any issues to the Lead Nurse on duty (or deputy) and where necessary contact the senior pharmacy technician for advice e.g., operational/clinical queries.
- Vaccines must not be handed out on the request of any PTHB department e.g., district nursing teams, without prior authorisation from the senior pharmacy technician.

10. Using Multiple Vaccines During a Vaccination Clinic

It is important to mitigate the risks associated with administration of multiple vaccines during a vaccination clinic, therefore certain measures must be put in place to minimise the risk of the wrong

vaccine / incorrect dose, being administered. All staff must be fully engaged in making sure that the vaccination process is safe.

- When planning vaccination sessions ensure that there is as much separation of the different brands of vaccine as is practically possible e.g., use separate vaccination lanes.
- Where using multiple vaccines during a vaccination session, the lead nurse must inform staff of the vaccines in use.
- The lead nurse must inform staff prior to a changeover to different vaccine types.
- Vaccinators must double check that the vaccine handed to them is the correct vaccine (particularly when different strengths of the same vaccine type are in use e.g., Comirnaty for adults / Comirnaty 5-11 years / Comirnaty for Infants)
- Inform admin staff when multiple vaccines are in use and ensure that the correct PILs are available for admin staff to hand out to citizens.

11. Managing Covid Stock Toward the End of the Day

From 3pm onwards (later, if the shift is longer), the member of staff supporting vaccine management, admin, and the lead nurse (or deputy), must liaise to identify the number of appointments scheduled for the remainder of the working day, versus how many doses are 'on the floor'.

To avoid waste, vaccine should only be removed from the fridge if it is certain that all the doses will be administered. Where waste may be unavoidable e.g., DNAs, the admin team may utilise the reserve list (if in place) to identify citizens who may be able to attend the centre at short notice to receive a vaccine.

11.1 Sharing Covid multidose vials at the end of the day

Where vials are shared (when shutting down workstations toward the end of the day), consider placing the vial in a neutral area (e.g., an empty vaccination workstation, fridge area, nurse office), and each vaccinator going there to draw up their own dose. Ensure the vial remains in the correct coloured tray with the required number of syringes, diluent/adjuvant (where applicable), swabs and vaccination cards.

Vaccinators should use the correct coloured tray to transport the syringe back to the vaccination lane. The syringe should not be re-sheathed but carefully placed back into the syringe packet. This must be done under the supervision of the clinical lead NB. A citizen must

be present at a vaccination lane before a dose is drawn up. Do not draw up vaccine in advance.

Alternatively, one registrant may draw up vaccine doses to hand out to vaccinators, as citizens present. As above, this should be done in a neutral area under the supervision of the clinical lead nurse. Ensure the vial remains in the correct coloured tray with the required number of syringes, diluent/adjuvant (where applicable), swabs and vaccination cards.

Vaccinators should use the correct coloured tray to transport the syringe back to the vaccination lane. The syringe should not be re-sheathed but carefully placed back into the syringe packet. NB. A patient must be present in a vaccination lane before a dose is drawn up. Do not draw up vaccine in advance.

12. Managing Covid-19 Vaccines During Hot weather

Vaccines must be stored and used within temperatures specified by the manufacturer and MHRA-authorised conditions of use, to ensure their safety, quality and efficacy.

Heat speeds up the decline in potency of most vaccines, therefore vaccine effectiveness cannot be guaranteed unless they have been stored at the correct temperature.

With increasing temperatures during summer, it is important to think about COVID-19 vaccines to ensure their continued safety, quality and efficacy.

Monitoring of temperatures in ambient preparation and administration areas is required e.g., any area where the vaccine is held after removal from cold storage (+2°C – +8°C).

Frequent measurements should be taken with a calibrated digital thermometer (up to three times a day in hot weather – see appendix B - Ambient Temperature Monitoring Log).

The higher the temperature the more frequent the monitoring needs to be:
If the temperature is greater than 22°C in the work area, monitoring should be hourly (see appendix B, Ambient Temperature Monitoring Log).

- Action must be taken to prevent temperatures exceeding 25°C

- If temperatures reach 25°C additional steps (see below) will need to be taken to protect the vaccines e.g., Unpunctured Spikevax vaccine can be stored for 24 hours up to 25°C following removal from the refrigerator. Punctured Spikevax vaccine may be stored for 6 hours up to 25°C (as of June 2025). See SmPC for vaccine in use to confirm specifics.

Optimise workflow and work area: Staff responsible for vaccine management at the vaccination clinic must manage workflows from storage to preparation and administration; to minimise the time the vaccine is outside cold storage and exposed to elevated temperatures. Remove only one vial at a time from the fridge/Labcold™portable vaccine carrier. Where possible, additional mechanical controls (e.g., portable air conditioning) should be used, either on a temporary or permanent basis, to maintain temperatures within the required range. NB. Use of fans and opening windows will improve conditions for staff but do not normally lower air temperatures, unless they move air from a cooler area to a warmer area. Consider restricting the number of people working or waiting in the vaccine preparation area, and removing non-essential electrical equipment, as this may reduce the temperature slightly.

In extreme circumstances and if temperatures are unable to be maintained below 25°C, contact the Senior Pharmacy Technician.

In this instance it may be necessary to provide the vaccinator with a tray containing a cool pack. Each VC will have a fridge in which cool packs are stored and can be used for this purpose. Contact the pharmacy stores team if extra cool packs are required.

Extra cool packs may be transported in Helapet vaccine carriers to outreach clinics during hot weather. Each Helapet must contain a data logger.

A tray containing the vaccine must be placed on top of the cool pack tray. This should keep the temperature of the vaccine sufficiently cool and below 25 C.

A new cool pack and tray should be provided each time a vaccinator requests a vaccine, or until the cool pack begins to lose its temperature.

Minimise the time the fridge door/Labcold™ portable vaccine carrier is open. Repeatedly opening the refrigerator/ Labcold™ portable vaccine carrier will allow warm air to enter. Make sure fridge doors/

Labcold™ portable vaccine carrier lids are securely closed as soon as possible after opening.

Previously used cool packs should be cleaned with a Clenil wipe and placed back into the fridge to cool down (do not reuse at the same vaccination clinic until sufficiently cooled). Once the vaccination clinic has ended, all cool packs must be cleaned and placed back into the fridge. The time that the cool pack will be ready for next use e.g., for use in Helapet vaccine porters must be indicated (24-hours after placing in the fridge).

An informal assessment of risk must be undertaken frequently as conditions change. Assessments should take place at the start of, periodically during, and after each vaccination session.

13. Products Requiring Ambient Temperature Storage

Medication must be stored in accordance with the manufacturer's instructions. For Ambient Temperatures storage, recommendations are between 15 and 25 degrees Celsius.

Vaccination Centres holding medication requiring ambient temperature storage include adrenaline, contained within anaphylaxis kits.

Both hot and cold temperatures can physically change medication which can adversely affect their potency; therefore, temperature monitoring must take place in those areas storing medication requiring ambient temperature storage conditions e.g. +15°C to +25°C. The recorded data must be saved in the relevant vaccine management Teams folder for easy retrieval.

Documenting a daily log of ambient temperatures in medication storage areas is a requirement of Health Inspectorate Wales (HIW) and is subject to inspection. This requirement is also stipulated in Patient Safety Notice (PSN055) (see Appendix B – Ambient Temperature Monitoring Log).

During periods of hot weather, temperatures must be monitored more frequently, as per Section 12.

Process:

- Record ambient temperature daily using a thermometer (VCs and at outreach clinics)

- If the temperature reaches +22°C, then monitoring must occur more frequently, as per Section 12.

For anaphylaxis kits:

- Ensure that the anaphylaxis kit has an expiry date of at least 2 months. If it does not, contact the Pharmacy Store team for advice.
- If the ambient temperature in the work area reaches +22°C, then a data logger must be placed inside the anaphylaxis kit, or in the case carrying the anaphylaxis kit.
- The data logger must remain there for the duration of the hot weather spell and downloaded as soon as the ambient temperature becomes stable at between +15°C to +25°C
- Save the data logger download in the relevant Teams channel and email the downloaded data to the Pharmacy Store team.
- The Pharmacy Store team will analyse the data and where appropriate recommend that the product expiry date be reduced. A label will be sent to the VC team lead with the reduced expiry date. This must be placed onto the affected anaphylaxis kit close to the original expiry date. It should not obscure any other information on the anaphylaxis kit.

14. Transport of Vaccine

14.1 Community Settings/Walkabouts

This section <u>MUST</u> be read in conjunction with:

- **PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines**
- **MMP 428 Use of Labcold™ Portable Vaccine Carriers,**
- **MMP 432 Use and Management of Vaccine Porters**

All SOPs can be accessed via the vaccine management SOP folder located in each vaccination centre.

- Vaccine may be transported to planned outreach clinics using Labcold™ portable vaccine carriers or for larger volumes of vaccine, using validated Helapet vaccine carriers.
- Labcold™ portable vaccine carriers transported in vehicles must be plugged into a power source for the entire journey and secured to avoid movement during transportation (see MMP 428 Use of Labcold™ Portable Vaccine Carriers for detailed information).
- Unused Covid vaccine returned to the VC from a community setting can be placed back into the front of the fridge provided

that the cold chain can be assured e.g., that the data logger download demonstrates that the cold chain has been maintained between +2°C to +8°C and must be marked with a cross and the date. Returned Covid vaccine must be placed at the front of the fridge to be used first within the VC setting. This is because there are limits on the number of times Covid vaccine can be transported. NB. Ensure that quantities of Covid vaccine transported to clinics within a community setting do not exceed the number of planned appointments for that day.

- Vaccine required for mop-ups or 'walkabouts' e.g. flu vaccine, can be transported using a validated Helapet vaccine porter and a data logger.
- A data logger must be used with both types of vaccine porters
- All data logger downloads must be saved in the relevant folder on Teams. Saved data must be named appropriately to ensure easy retrieval e.g. name of venue / date / vaccine porter used (i.e. Helapet/Labcold).
- Temperature monitoring must take place when Labcold vaccine carriers are used (see appendix C)
- A Helapet vaccine monitoring log must be completed where using Helapet vaccine carriers in community settings (see Appendix D)
- A reference number must be raised by VC staff for all vaccine leaving the vaccination centre and the details added to the vaccine management Excel spreadsheet. Access here: VC VACCINE RECORD OUTREACH_CARE HOMES etc
- Vaccine may be removed from the fridge on multiple occasions for use in a community setting PROVIDING that a Labcold™ portable vaccine carrier/validated Helapet vaccine porter and data logger is used and that the cold chain can be assured e.g., the data logger data is downloaded and analysed on return to the VC and that the temperature has remained between +2°C to +8°C for the duration that it has been outside of the VC.
  NB. **All** cold-chain products that have been taken into the community and have been returned to the fridge must be easily identifiable; therefore, the box must be marked with a small cross and the date the item was removed added alongside it. This must be done every time the box of vaccine is returned to the fridge from a community setting.

  NB. There is no requirement to transfer or receipt Covid/flu vaccines on WIS to outreach clinics / walkabouts / mop-ups, **where a Labcold™ portable vaccine carrier is being used to store the vaccine** (a record of vaccine movement between sites will be documented on the VC vaccine management Excel

spreadsheet)**.** However, stock checks must be updated on WIS at the VC whenever vaccine is removed and returned.

NB. Movement of all other vaccine types where functionality on WIS does not allow record keeping, must be documented using the appropriate vaccine stock management Excel spreadsheet.

Using Refrigerators in a community setting (rare)

If using a fridge in a community setting (e.g., if using a refrigerator in another PTHB department e.g., Outpatients fridge to store vaccine to use at an outreach vaccination clinic) it is important to ensure that the fridge has maintained its temperature of between +2°C to +8°C, before loading with vaccine e.g., check that the manual fridge temperature record has been kept up to date and that the recorded temperatures have remained within a range of +2°C to +8°C. Take a fridge temperature recording e.g., min, max & actual temperature before commencing the clinic, then reset.

15. Further Information

For all vaccines:

- Once all the doses have been withdrawn from a vial / administered from a pre-filled syringe / nasal spray, or if the expiry has been exceeded, discard the used vaccine vial/syringes/nasal spray into a yellow lidded sharps bin.

- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.

- Do not pool excess vaccine from multiple dose vials.

- Empty outer cartons must be cut up disposed of in a secure manner e.g., into the recycling waste stream.

To minimise the risk of vial stoppers coring and particles entering the vial (multidose vials):

- Insert the needle through a fresh point in the inner ring of the vial stopper each time.
- Each time the vial bung is punctured this should be in a different location to previous points of puncture on the bung. Work methodically around the inner ring of the vial stopper tracking previous puncture points.

- Do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

Safety Check

Prior to issuing vaccines at a vaccination session, inspect for:

- Any obvious breakages.
- No evidence of cracks in glass, leakage, or other damage.
- The contents of the vial are fully thawed (i.e. Covid vaccine).
- The vaccine contains no visible particles.

16 Vaccine Consumables

- Covid vaccine consumables and Patient Information Leaflets (PILs) will be delivered to sites in quantities comparable to the vaccine supplied.
- Stocks of consumables should be stored in a suitably clean, dry environment, and in a manner that supports safe working and ease for access and stock checks.
- Stocks of consumables which are not actively in use should be stored in a single location within each VC wherever possible.
- **NEVER LET CONSUMABLE STOCKS RUN LOW**. When stocks of syringes drop to 20 boxes (2000 syringes), inform the senior pharmacy technician immediately, who will facilitate an order.
- If there are any discrepancies on receipt of a consumable order, immediately inform the senior pharmacy technician.
- In the unlikely event that stocks of consumables may be insufficient to support scheduled vaccinations, this must be raised with the VC lead nurse and the senior pharmacy technician as a matter of urgency.
- Swabs and vaccination cards must be ordered by VC teams separately. Vaccination cards are available to order from Public Health Wales Health Information Resources - Public Health Wales (nhs.wales)

17 Vaccine Spillages

- If spillage of vaccine occurs, gloves should be worn, and the spillage soaked up with paper towels immediately. These should all be put into a yellow clinical waste bag.
- Sharps should be put into a sharps bin for disposal.
- The area should then be cleaned according to the local Disinfection Policy.

- Spillage on the skin should be washed off thoroughly using soap and water.
- Splashes in the eyes should be irrigated with sterile 0.9% sodium chloride solution and medical advice sought immediately. Report via Datix and escalate to the lead nurse.

18 Punctured Covid Vaccine Vials

Punctured vials of Covid vaccine may be transported in a validated vaccine porter at +2° to +8°C (see SmPCs for information on transportation times for each vaccine, as they differ) e.g., when transporting vaccine between care homes during mop-up phases, to avoid wasting doses.

However, the vaccines contain no preservative, and the method of puncture cannot preclude the risk of microbial contamination, so Specialist Pharmacy Service (SPS) advises that <u>transport of punctured vials should not be routine</u>.

The decision to move punctured vials of vaccine between locations within the same legal entity must include an assessment of the risk of microbial contamination and proliferation versus risk of wastage and loss of opportunities to administer vaccines at alternative locations.

Any decision to move punctured vials must be made locally under the direction of the Chief Pharmacist. The specific circumstances will be taken into account, using appropriate risk control measures such as temperature control, infection prevention and control, and a means to identify that the vial has been punctured.

19. 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.

20. References

PTHB MMP 010 Safe and Secure Management of Refrigerated Medicines and Vaccines Medicines Management - SOPs - All Documents (sharepoint.com)

Electronic Medicines Compendium Home - electronic medicines compendium (emc) accessed 03/06/2025

Specialist Pharmacy Service. Handling of Covid-19 vaccines, published 26/03/2025 Handling of COVID-19 vaccines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice accessed 03/06/2025

Appendix A Vaccination Centre Fridge & Stock Monitoring v4.0

Date: VC:	FRIDGE MONITORING (REPORT EXCURSIONS TO PHARMACY STORE TEAM IMMEDIATELY)				
	MAX Temp	MIN Temp	Actual Temp	Reset (tick)	Signature (+ Any Comments)
Start of Shift TIME:					
During Shift TIME:					
End of Shift TIME:					

Vacc. Lane No	Time Vial Removed from Fridge/ Porter	Removed By (PRINT NAME INITIALLY, THEN INITIAL GOING FORWARD)	No. of Vials/ Syringes Removed from Fridge	RUNNING TOTAL								
				Spikevax (LP 8.1)	Comirnaty (LP 8.1) 10 For Children 5 – 11 years	Comirnaty (LP 8.1) 3 (three) for Infants 6M-4Y	Comirnaty 30 (LP 8.1) (12Y-17Y)	RSV (Abryvso)				
INITIAL COUNT:												
	:		1									
	:		1									
	:		1									

Vacc. Lane No	Time Vial Removed from Fridge/ Porter	Removed By (PRINT NAME INITIALLY, THEN INITIAL GOING FORWARD)	No. of Vials/ Syringes Removed from Fridge	Spikevax (LP 8.1)	Comirnaty (LP 8.1) 10 For Children 5 – 11 years	Comirnaty (LP 8.1) 3 (three) for Infants 6M-4Y	Comirnaty 30 (LP 8.1) (12Y-17Y)	RSV (Abryvso)				
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Appendix B

Ambient Temperature Monitoring Chart Month _____

Ambient temperatures should be monitored at least 3 times daily (preferably morning, midday and close of play).
If the ambient temperature rises above 22°C, hourly monitoring must be undertaken using the additional columns below.

	Morning		Midday		Afternoon		Additional Monitoring When Temperature Rises Above 22°C								
Date	**Time**	**Temp**	**Time**	**Temp**	**Time**	**Temp**	**Time**	**Temp**	**Time**	**Temp**	**Time**	**Temp**	**Time**	**Temp**	**Comments**
1															
2															
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Appendix C

Labcold Portable Fridge Monitoring LOG v2

Fill in white boxes, add temperatures and sign

Date: **LOCATION:** **Time Labcold Switched on:** **Time Labcold Reached a Stable Temperature of Between +2˚C to +8˚C:** **Time Data Logger Placed inside:** **Time vaccine placed in Labcold:** **Time last vaccine used (if vaccine returned to VC in Labcold, mark n/a):**	**Temperature**	**Signature (+ Any Comments)**
Start of Vaccination Clinic **TIME:**		
During Clinic **TIME:**		
During Clinic **TIME:**		
End of Clinic **TIME:**		

Please scan and save on return to VC with associated data logger download

Appendix D

Helapet Vaccine Porter Temperature Monitoring LOG v1

Complete white boxes.

Date:	**Time**	**Signature (+ Any Comments)**
VC LOCATION:		
OUTREACH LOCATION:		
Time vaccine placed inside Helapet:		
Time Data Logger Placed inside Helapet:		
Time last vaccine removed from Helapet (if vaccine returned to VC in Helapet, mark as n/a):		

Please scan and save on return to VC with associated data logger download.