

## Use of Labcold™ Portable Vaccine Carriers Standard Operating Procedure.

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2	Update to section 8 – Mitigating Risk. Removal of Helapet vaccine porter as back up at outreach clinics in the event of a failure of the Labcold™ Portable Vaccine Carrier. Addition of a Labcold™ Vaccine Portable Carrier to be taken to outreach clinics in place of a Helapet vaccine porter.	Aug 2024

### Engagement & Consultation

#### Key Individuals/Groups Involved in Developing this Document

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#### Circulated to the following for Consultation

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11/01/2024	Chief Pharmacist
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	Service Development Manager, Immunisation & Vaccination
12/08/2024	PA to Head of Service: Public Health Programmes and Projects for dissemination to ODG members
22/08/2024	Vaccination Programme Operational Development Group

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## **1 Introduction**

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

It is mandatory for all staff members involved in the process of transportation of refrigerated medicines and vaccines to always follow this standard operating procedure.

The efficacy and safety of pharmaceuticals, including vaccines, requiring controlled low temperature storage ultimately depends on the maintenance of temperatures within the manufacturers' recommended range, typically +2°C to +8°C. If the storage recommendations are not followed, manufacturers can disclaim responsibility for any apparent failure of the product.

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

## **2. Objective**

- To clearly establish standards for the safe movement of refrigerated medicines and vaccines using Labcold™ portable vaccine carriers.
- To describe the procedure for use of Labcold™ portable vaccine carriers in a clinic setting.
- To describe the procedure for recording the temperature of Labcold™ portable vaccine carriers to provide assurance that medicines and vaccines are stored within the manufacturers recommended temperature range.
- To take appropriate corrective and timely action in the event of a Labcold™ portable vaccine carrier temperature excursion outside of the cold chain range of +2°C to +8°C.

## **3. Definitions**

- **PTHB** – Powys Teaching Health Board

- **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.
- **Medicine** – a substance used for treating, preventing or diagnosing disease, for contraception, inducing anaesthesia or modifying normal physiological function.
- **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.

#### 4. Role / Responsibilities

##### 4.1 Service Lead

The Service Lead must:

- Ensure all staff read and understand this procedure.

##### 4.2 Senior Nurse/Clinical Lead

- The senior nurse is responsible for ensuring that all appropriate staff for whom they have responsibility (i.e., anyone who has any involvement with using Labcold™

portable vaccine carriers) have undertaken cold chain training, have been signed off as competent in the use of Labcold™ portable vaccine carriers and have read, understood and adhere to the standards in this SOP. They are also responsible for managing any temperature excursion that may occur.

#### **4.3 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores**

- The senior pharmacy technician is responsible for arranging regular review to monitor compliance with this procedure, providing advice on the safe and secure use of Labcold™ portable vaccine carriers and supporting the investigations into any disruptions to the cold chain. They are also responsible for providing advice on suitability of medicine/vaccine use following temperature excursions.

#### **4.4 Other Staff**

- All staff employed by Powys Teaching Health Board (PTHB) who are involved in movement of refrigerated medicines and vaccines using Labcold™ portable vaccine carriers in all healthcare settings are responsible for undertaking cold chain training, Good Distribution Practice (GDP) training (where applicable – see section 6), adhering to this SOP, maintaining competence, and reporting and reacting to temperature excursions. Evidence of competencies must be made available on request from the Medicines Management Team.

### **5. Labcold™ Portable Vaccine Carriers and Data Loggers**

#### **5.1 Overview**

Labcold™ portable vaccine carriers are designed to maintain the cold chain when it is considered necessary to move refrigerated medicines/vaccines from one location to another. They are powered by both mains and vehicular 12-volt power sources. The unit has a clear digital temperature display.

Labcold™ portable vaccine carriers used in PTHB must be calibrated before use (see section 5.3)

When Labcold™ portable vaccine carriers are in use, calibrated data loggers must be placed inside for extra temperature security (see section 5.2)

Labcold™ portable vaccine carriers are suitable for use within PTHB to support the administration of vaccines at scheduled clinics away from base e.g. outreach clinics, school vaccinations sessions.

**NB:**

- Labcold™ portable vaccine carriers are not designed to be run for extended periods of time (i.e. they must not be used in place of a medical grade refrigerator for routine storage of medicines/vaccines and are designed only for use at a vaccination clinic shift e.g. outreach / school immunisations / care homes / housebound.
- Labcold™ portable vaccine carriers **do not** hold temperature when not connected to power source.

## 5.2 Data Loggers

For extra temperature security, Labcold™ advise that data loggers are placed inside Labcold™ portable vaccine carriers when in use, to track the temperature of the unit.

These devices can be set up to take regular readings (PTHB data loggers must be set to 5-minute intervals). This will provide a clear picture of temperature fluctuations within the unit.

This data is stored on the Log Tag (up to 56 days) and is downloadable via the Log Tag Analyser app:

<https://logtagrecorders.com/software/lta3/download/> **NB. I.T will need to be contacted to download the application to your device.**

A PowerPoint training presentation on the use of data loggers can be accessed here: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#)

A crib sheet detailing use of data loggers, how to download data and where to save data electronically, can be found here: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#)

### 5.3 Procurement

Before purchasing a new Labcold™ portable vaccine carrier and/or data logger, the Medicines Management Team should be contacted for advice. [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)

Information on the Labcold™ portable vaccine carrier can be accessed here: [Labcold Vaccine Carrier RPDF0012F - Labcold](#)

Prior to first use, calibration must be undertaken for both Labcold™ portable vaccine carriers and data loggers, **this can be arranged in advance with the supplier when ordering.** Labcold™ portable vaccine carriers and data loggers must be asset tagged and registered onto the PTHB Medical Device Asset Management System (e-quip) Information Asset Register (IAR) [Information Asset Register \(IAR\) \(sharepoint.com\)](#)

It is essential that the service lead/senior nurse/clinical lead provide details of all newly purchased Labcold™ portable vaccine carriers and data loggers to the Medicines Management Team, who will keep a record and ensure that annual servicing/calibration requirements are met. Please email details to:

[info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk) **NB:** Failure to do this will mean that the vaccine carrier/data logger will not be calibrated on an annual basis, potentially compromising the safe storage of medicines requiring cold storage.

Although Labcold™ portable vaccine carriers and data loggers are logged with the Medicines Management Team for annual servicing/calibration arrangements, all departmental Labcold™ portable vaccine carriers and data loggers must be checked to ensure that annual calibration is up to date (i.e. that they have been calibrated within the last 12 months) – this is the responsibility of the Head of Service and any staff who use Labcold™ portable vaccine carriers and data loggers. There will be a sticker on the Labcold™ portable vaccine carrier indicating the date of the last calibration/when next calibration is due. The Medicines Management Team will organise re-calibration of all Labcold™ portable vaccine carriers and of data loggers, however if any unit is over-due calibration it must be reported to the Medicines Management Team immediately and must not be used until calibration has taken place. Email: [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)



## **6. Training**

Before using Labcold™ portable vaccine carriers and data loggers', staff must have received training in their use and be signed off as competent by the senior nurse/clinical lead/pharmacy technician. Documents to support this i.e. a competency checklist, can be located here: [Medicines Management - Labcold Portable Vaccine Carriers - All Documents \(sharepoint.com\)](#).

Signed competency checklists must be saved in the Labcold™ Portable Vaccine Carrier folder [Medicines Management - Labcold Portable Vaccine Carriers - All Documents \(sharepoint.com\)](#)

All staff must also be up to date with all cold chain training i.e:

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

### **[000 Vaccine Storage](#)**

All staff involved with transportation of medicines/vaccines in a Labcold™ portable vaccine carrier 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'. For information on how to access this training contact Nikki Mathers via [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)

## **7. Transporting Refrigerated Medicines/Vaccines in a Labcold™ Portable Vaccine Carrier**

### **7.1 Preparing a Labcold™ Portable Vaccine Carrier before use.**

- Prior to placing any refrigerated medicine/vaccine into the vaccine carrier, the unit must be plugged into the mains and switched on for at least 20 minutes to allow the unit to cool.
- The vaccine carrier must reach and maintain a stable temperature of between 2°C - 8°C before packing with medicines/vaccines.
- Set up or reconfigure a data logger, ready for use. Training available here: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#)
- Once the temperature of the Labcold™ portable vaccine carrier has reached between 2°C - 8°C and the temperature remains stable, place the prepared data logger into the vaccine carrier.

- Swiftly pack the vaccine carrier with the required amount of vaccine and securely close the lid. NB. Do not overfill, do not remove the vaccine from its original pack. Only take enough vaccine required for the session to avoid waste.

## **7.2 Transporting the Labcold™ portable vaccine carrier from base to venue<sup>1</sup>.**

- The Labcold™ portable vaccine carrier will not hold its temperature when unplugged from the mains supply, it is therefore important to transfer the vaccine carrier safely and quickly into the vehicle which will be transporting the vaccine carrier to the intended venue.
- Using the 12v lead, plug the vaccine carrier into the 12v power source in the vehicle (i.e. cigarette lighter).
- Ensure that you have the mains power lead with you, to plug the vaccine carrier into the mains at the venue.
- Keep the vaccine carrier upright at all times and safely secured to avoid movement i.e. with a seat belt or in the footwell.
- Where possible, travel with a colleague to ensure that the vaccine carrier is safely secured and to allow the temperature to be monitored during the journey.
- On arrival at the venue, check that the temperature on the digital display is stable between 2°C - 8°C.
- Unplug the vaccine carrier from the vehicle power source then swiftly and safely transport the vaccine carrier into the venue and plug into a mains socket.
- Check that the temperature on the digital display remains stable between 2°C - 8°C.

## **7.3 Labcold Portable Vaccine Carrier - In use.**

- Before starting the clinic session, manually record the vaccine carrier temperature. Do this again at lunchtime and at the end of the day. The manual temperature record must be kept until the cold chain can be assured at the end of the day via the data logger download.
- Keep the vaccine carrier lid open for the absolute minimum amount of time to ensure that the unit maintains its temperature (i.e. only open when removing vaccine).

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<sup>1</sup> PTHB staff who transport refrigerated medicines/vaccines within the organisation must ensure that they are legally covered to do so by their motor vehicle insurer (insured for business use as well as domestic use). Where possible use PTHB pool cars or dedicated PTHB transport .

- Visually check the temperature on the digital display of the vaccine carrier throughout the day.
- See section 8, Mitigating Risk for instruction on the actions to take should the Labcold™ portable vaccine carrier fail at any point i.e. a temperature excursion.
- At the end of the session, follow section 7.2 to return any unused product back to base.

#### **7.4. Return to base.**

- On return to base, remove the data logger from the Labcold™ portable vaccine carrier.
- Remove any unused product from the vaccine carrier, mark all sides of the box with a cross, date it and return to the fridge (see PTHB MMP 427 'Safe and Secure Management of Refrigerated Medicines/Vaccines' for information on management of returned product)
- Download the data from the data logger. Training available here: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#)
- Immediately analyse the data download to check for any temperature deviations throughout the day (i.e. below 2°C or above 8°C).
- If the temperature has remained stable (between 2°C - 8°C), then save the download in the relevant folder on the SharePoint drive: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#) Save the download as location (i.e. venue that vaccination took place) and date.
- If the data download indicates that there has been a temperature deviation during the course of the day, quarantine any returned stock in the refrigerator and report the incident immediately to the service lead and the Medicines Management Team (refer also to PTHB SOP [MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines v1.1.pdf](#))

#### **8. Mitigating Risk**

To ensure compliance with the cold chain in an emergency i.e. failure of the Labcold™ Portable Vaccine Carrier when in use, a second empty Labcold™ Portable Vaccine Carrier must be transported to the clinic, alongside the Labcold™ Portable Vaccine Carrier in use. It is advisable that the emergency Labcold™ Portable Vaccine Carrier is transported in the boot of the car for safety. In the event of a failure of the Labcold™ portable vaccine carrier, the vaccine can be swiftly transferred to the emergency Labcold™ Portable Vaccine Carrier,

thus maintaining the cold chain. Ensure that a data logger is placed into the emergency vaccine porter to allow any unused vaccine to be returned to stock, providing the data logger download demonstrates that the cold chain has been maintained between 2°C - 8°C. In the event of an emergency whereby medicine/vaccine has been transferred to the emergency Labcold™ Portable Vaccine Carrier, inform the service lead and pharmacy lead for vaccination/immunisation: Nikki Mathers via: [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)

Alternatively, in the event of a failure of the Labcold™ portable vaccine carrier, medicines/vaccines may be transferred to a refrigerator at the clinic, if one is available, providing that the cold chain for that refrigerator can be assured i.e. there is evidence that the refrigerator temperatures (actual/minimum/maximum) have been recorded daily, reset after each temperature reading and that the temperature has remained stable between 2°C - 8°C. This information will be available from the department's manual daily refrigerator temperature monitoring sheet. If the temperature of the refrigerator cannot be assured, report to the Medicines Management Team via [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk) to investigate.

## **9. Cleaning**

Labcold™ portable vaccine carriers must be wiped clean inside and out with a Clinell wipe after each use. Take care not to damage any delicate areas and entry points for cables.

Data loggers, Helapet vaccine porters and cool packs should also be wiped clean with a Clinell wipe on return to base. For cleaning of Helapet vaccine porters and cool packs refer to [Medicines Management - SOPs - All Documents \(sharepoint.com\)](#), for access email Nikki Mathers via [info.medicinesmanagement.powys@wales.nhs.uk/](mailto:info.medicinesmanagement.powys@wales.nhs.uk/)

Store all associated equipment i.e., leads, straps, manual etc, with the vaccine carrier. Store in a safe, secure location.

## **10. Monitoring Compliance / Audit / Review**

Compliance with this SOP will be audited during annual pharmacy audits in vaccination centres. All other departments using Labcold™ Portable Vaccine Carriers within PTHB must self-audit annually and report the results to the Medicines Management Team via

[info.medicinesmanagement.powys@wales.nhs.uk/](mailto:info.medicinesmanagement.powys@wales.nhs.uk/) The audit tool can be found here: [Labcold Portable Vaccine Carriers](#)

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

## **11. References**

Labcold™ Medical & Scientific Refrigeration. Labcold™ Vaccine Carrier [Labcold Vaccine Carrier RPDF0012F - Labcold](#) (accessed 09/01/2024)

PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines [Medicines Management - SOPs - All Documents \(sharepoint.com\)](#)