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Use and Management of Helapet Vaccine Carrier Systems

Standard Operating Procedure.

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Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
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1	Initial Issue	08/04/2024
2	Update to Section 5.2 Data Loggers and Thermometers – caveat for vaccination team re. use of data loggers only rather than data loggers and thermometers. Update to section 8.1 Preparing a Helapet Vaccine Porter Before use; note added to clarify that the vaccination team use data loggers only (not thermometers) when transporting vaccine into the community for short periods of time.	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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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.

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

For access to any documents/paperwork referred to in this SOP email Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk/

2. Objective

- To clearly establish standards for the safe movement of refrigerated medicines and vaccines using recognised validated vaccine porters and cool packs.
- To describe the procedure for use of validated vaccine porters and cool packs in a clinic setting.
- To describe the use of data loggers/thermometers.
- To describe the procedure for recording the temperature of validated vaccine porters 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 vaccine porter 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

	<p>The Service Lead must:</p> <ul style="list-style-type: none"> • Ensure all staff read and understand this procedure and that all relevant staff have been appropriately trained.
	<p>4.2 Senior Nurse/Clinical Lead</p> <ul style="list-style-type: none"> • The senior nurse is responsible for ensuring that all appropriate staff for whom they have responsibility (i.e., anyone who has any involvement with validated vaccine porters and cool packs) are trained in their use, have undertaken cold chain training, and have read, understood and adhere to the standards in this SOP. They are also responsible for managing any temperature excursion that may occur. <p>4.3 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores</p> <ul style="list-style-type: none"> • 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 validated vaccine porters and cool packs 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. <p>4.3 Other Staff</p> <ul style="list-style-type: none"> • All staff employed by Powys Teaching Health Board (PTHB) who are involved in movement of refrigerated medicines and vaccines using validated vaccine porters and cool packs 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.
	<p>5. Validated vaccine porters and Data Loggers / Thermometers</p> <p>5.1 Overview</p> <p>Validated vaccine porters are designed to maintain the cold chain when it is considered necessary to move refrigerated</p>

medicines/vaccines from one location to another. Powys Teaching Health Board (PTHB) use Helapet validated vaccine porters along with Medicool® cool packs approved for use with this vaccine porter.

Where Helapet vaccine porters are used, calibrated data loggers and / or a thermometer must be placed inside to monitor temperature during transport/use (see section 5.2)

Alternatively Labcold™ portable vaccine carriers can be used to transport medicines/vaccine. Refer to MMP 428 Use of Labcold™ Portable Vaccine Carriers [Medicines Management - SOPs - All Documents \(sharepoint.com\)](#)

5.2 Data Loggers/Thermometers

It is a requirement that vaccines are continuously monitored, therefore, for temperature security, data loggers and/or a thermometer must be placed inside vaccine porters, to monitor the temperature of the unit.

The Medicines Management Team recommend that data loggers are used with Helapet vaccine porters in conjunction with a minimum/maximum thermometer (Vaccination Team: see also section 8.1 Preparing a Helapet vaccine porter before use; bullet point 7). Data loggers 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 vaccine porter.

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 \(sharepoint.com\)](#)

A data logger is preferable for use with vaccine porters but a maximum/minimum thermometer should also be used alongside as a visual indicator that the temperature range is being maintained.

If a data logger is not available, then a maximum/minimum thermometer can be used. The thermometer reading must be monitored and recorded three times during use i.e. during a vaccination clinic (see appendix A – Temperature Monitoring Log). At the end of a session the temperature monitoring log must be scanned and saved.

6. Procurement

Before purchasing Helapet vaccine porters, Medicool® cool packs data loggers or thermometers, the Medicines Management Team should be contacted for advice.

info.medicinesmanagement.powys@wales.nhs.uk

Information on Helapet Vaccine Carrier Systems can be accessed here: [VaccinePorter® Carrier Systems - Helapet Ltd.](#)

It is essential that the service lead/senior nurse/clinical lead provide details of all newly purchased 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 **NB:** Failure to do this will mean that the data logger will not be calibrated on an annual basis, potentially compromising the safe storage of medicines requiring cold storage.

Although data loggers are logged with the Medicines Management Team for annual servicing/calibration arrangements, all departmental 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 data loggers. The Medicines Management Team will organise re-calibration of all data loggers, however if any data logger 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

7. Training

Before using Helapet vaccine porters, Medicool® cool packs, data loggers' and minimum/maximum thermometers, staff must have received training in their use.

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 Helapet vaccine porters 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

8. Transporting Refrigerated Medicines/Vaccines in a Helapet Vaccine Porter

8.1 Preparing a Helapet Vaccine Porter before use.

Only approved and validated medical grade vaccine porters and cool packs must be used, to ensure the cold chain is maintained throughout the transportation process.

Domestic cool boxes must never be used to store or transport vaccines or other products requiring refrigeration.

It is important to note different sized vaccine porters require different sized and quantities of cool packs (see appendix B)

- Ensure that the vaccine porter has been cleaned before use i.e. with a Clenil wipe, before placing any refrigerated medicine/vaccine into the vaccine porter.
- Clean cool packs can be taken from the refrigerator provided they have been cooled for 24 hours prior to use. Check cool packs are intact and show no signs of leaking.
- Place the required number of cool packs for the vaccine porter in use on the base of the system and on each side of the system (see appendix B)
- Line with a layer of bubble wrap.
- Place the medicines/vaccine into the vaccine porter, ensuring that any deadspace is filled with packing material (i.e. bubble wrap, to avoid movement of product during transport).
- Set up or reconfigure a data logger, ready for use. Training available here: [Medicines Management - Data Loggers - All Documents \(sharepoint.com\)](#)
- Ideally a data logger and thermometer should be placed into the vaccine porter with the medicine/vaccine. NB. PTHB

vaccination teams use **data loggers only** to transfer vaccine into community settings where vaccine will not be stored in Helapet vaccine carriers for more than a few hours e.g. flu walkabouts, care home mop-ups.

- If a data logger is not available, place a correctly set thermometer into the unit (place the probe inside the vaccine porter with the product, place the display unit on the outside in the vaccine porter carrying case plastic pocket). See appendix C How to reset thermometers.
- Place a layer of bubble wrap on top of the product then place the required number of cool packs for the vaccine porter in use on top of the medicine vaccine (see appendix B)
- Place the polystyrene lid on the vaccine porter, ensuring the fit is secure, then close the outer carrying case lid immediately.
- Ensure that all sides of the velcro of outer carrying case lid is securely fastened.
- During transport the vaccine porter lid must be sealed with a security tag. Secur-Pull Breakable Seals can be purchased from Distinctive Medical Products, product code SKU:7908-10 (blue seals)
- Only open the vaccine porter when necessary and remember to re-seal immediately.
- Where there is any doubt that cold chain has not been maintained, products should not be used until further advice has been sought from the Medicines Management Team info.medicinesmanagement.powys@wales.nhs.uk

8.2 Transporting the Helapet vaccine porter from base to venue¹.

- Ensure that a data logger has been placed in the Helapet vaccine carrier.
- Keep the vaccine porter upright at all times and safely secured to avoid movement i.e. with a seat belt or in the footwell. It is advisable that Helapet vaccine carriers are transported in the boot of the car for safety.

9. Helapet Vaccine Porter – Use at Vaccination Clinics.

- Before starting the clinic session, manually record the thermometer temperature (minimum, maximum and actual),

¹ 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 .

then reset. 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 (see appendix A).

- Keep the vaccine porter lid open for the absolute minimum amount of time to ensure that the unit maintains its temperature (i.e. only open when removing vaccine).
- Visually check the temperature of the thermometer throughout the day.
- At the end of the session, follow section 9.1 to return any unused product back to base.

9.1. Return to base.

- On return to base, remove the data logger from the Helapet vaccine porter.
- Remove any unused product from the vaccine porter, mark all sides of the box with a cross, date it and return to the fridge (see PTHB MMP 010 '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](#))

10. Labelling a Helapet Vaccine Porter

- Products should be packed into a vaccine porter as close as possible to the pre-arranged collection time.
- Attach an address label to the vaccine porter lid. Supporting documentation can be accessed here: [Medicines Management -](#)

[Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#)

- Add the delivery destination, the date, and the vaccine porter number to the address label.
- **Add the vaccine porter expiry time to the address label (8 hours post-packing).**
- All vaccine porters must be clearly labelled 'Vaccines: refrigerate immediately on receipt'

For further advice on the use of Helapet vaccine porters and cool packs refer to PTHB SOP [MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines v1.1.pdf](#))

11. Checks of the Vaccine Porter System

- A visual squeeze check will need to be carried out before re-using each Medicool pack to ensure there is no loss of liquid. A weight check should be performed periodically (every 6 months). If the cool pack is $\pm 20g$ different to the weight shown on the cool pack instructions or shows any signs of leaking, then it is recommended that it is disposed of.
- Any chipped or broken polystyrene inners must be replaced before use as this can affect the thermal performance of the vaccine porter. Each polystyrene inner should be thoroughly checked for any signs of damage before each use. If damage is present, then the polystyrene inner should not be used.
- Where departments have a stock of more than one vaccine porter their use must be rotated.

12. Cleaning

Helapet vaccine porters, cool packs and data loggers/thermometers must be wiped clean with a Clinell wipe on return to base.

- Remove any laminated signs from the outer pockets of the vaccine porter and wipe with a Clinell wipe.
- Undo the outer case of the vaccine porter. Remove the inner polystyrene lid and take out the cool packs
- Wipe the cool packs with a Clinell wipe and allow to air dry.
- Clean cool packs should be placed back into the fridge to cool for a minimum of **24 hours**. The date and time the cool packs were cleaned and the date and time they will be ready for use must be indicated on the cool pack cleaning and refrigeration form located here: [Medicines Management - Cool Packs - All](#)

[Documents \(sharepoint.com\)](#) The form must be placed on top of the cool packs in the refrigerator.

- Wipe the polystyrene lid and inner with a Clenil wipe, inspect for signs of damage and wear and tear. Damaged lids and inners should be replaced.
- Wipe the outer carry case of the porter using a Clinell wipe.
- Place all clean items in a safe, secure location for the next use.
- Document that the cleaning process has been completed (see appendix D)

13. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits in vaccination centres. All other departments using Helapet Vaccine Porters within PTHB must self-audit annually and report the results to the Medicines Management Team via info.medicinesmanagement.powys@wales.nhs.uk/ The audit tool can be found here:

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

14. References

Vaccine Porter Carrier Systems [VaccinePorter® Carrier Systems - Helapet Ltd.](#)

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

PTHB MMP 428 Use of Labcold™ Portable Vaccine Carriers [Medicines Management - SOPs - All Documents \(sharepoint.com\)](#)

Appendix A

Vaccine Porter Temperature Monitoring Log (Between 2-8C) v 1.0

Session Location

Session Lead **Session Date**

Session Time: **Vaccine in Use:**

COMMENTS:

Time	Actual temp	Minimum temp	Maximum temp.	Reset (where applicable)	Sign and print name

Appendix B

Vaccine Porters - Instructions for Use

Wipe vaccine porter inside and out with Clenil wipe prior to use. Cool packs must have been cooled in the refrigerator for 24 hours prior to use. Check cool packs are intact and show no signs of leaking.

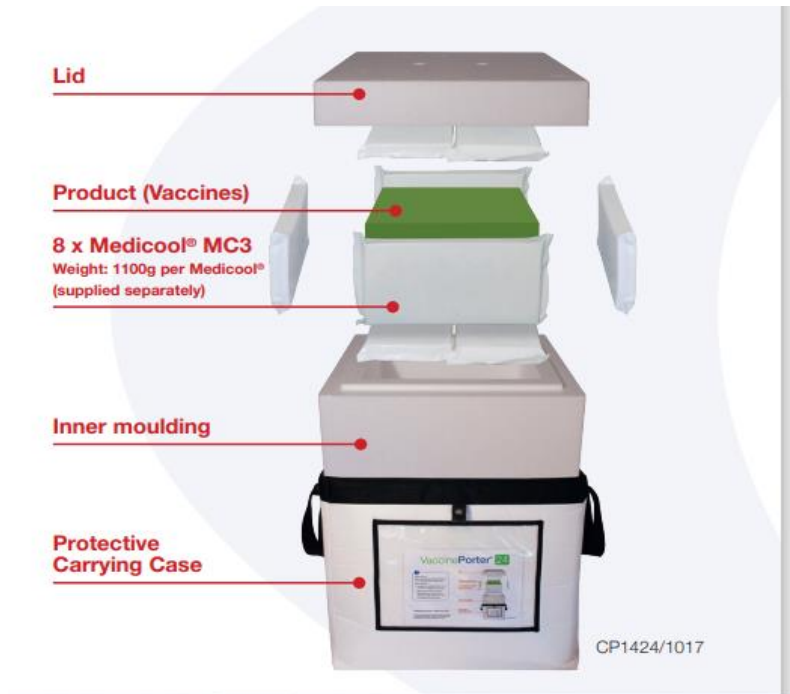
Large Vaccine Porter

- **8 large** cool packs in total

Instructions for Use

Pack and seal the vaccine porter swiftly, as follows:

- Place 2 x large cool packs on the base of the system.
- Place 1 x large cool pack on each side of the system, to surround the product load.
- Line with a layer of bubble wrap.
- Place the product to be transported in the centre of the vaccine porter.
- Fill any dead space in the vaccine porter with packaging material i.e. bubble wrap
- Insert data logger/thermometer into the porter as described in this SOP.
- Place a layer of bubble wrap on top of the product then place 2 x large cool packs on top of the bubble wrap.
- Place the polystyrene lid securely onto the system and ensure it is sealed by closing the outer carrying case immediately (ensure that the Velcro fastening is securely sealed).
- Only open the vaccine porter if necessary and remember to re-seal as soon as possible.



Medium Vaccine Porter

- 14 **small** cool packs in total

Instructions for Use

Pack and seal the vaccine porter swiftly, as follows:

- Place 4 x small cool packs on the base of the system.
- Place 2 x small cool packs across both of the longest sides of the system and 1 x small cool pack on both of the shortest sides of the system, to surround the product load.
- Line with a layer of bubble wrap.
- Place the product to be transported in the centre of the vaccine porter.
- Fill any dead space in the vaccine porter with packaging material i.e. bubble wrap
- Insert data logger/thermometer into the porter as described in this SOP.
- Place a layer of bubble wrap on top of the product then place 4 x small cool packs on top of the bubble wrap.
- Place the polystyrene lid securely onto the system and ensure it is sealed by closing the outer carrying case immediately (ensure that the Velcro fastening is securely sealed).
- Only open the vaccine porter if necessary and remember to re-seal as soon as possible.



Small Vaccine Porter

- **6 small** cool packs in total

Instructions for Use

Pack and seal the vaccine porter swiftly, as follows:

- Place 1 x small cool pack on the base of the system and 1 x small cool pack on each side of the sides, to surround the product load.
- Line with a layer of bubble wrap.
- Place the product to be transported in the centre of the vaccine porter.
- Fill any dead space in the vaccine porter with packaging material i.e. bubble wrap
- Insert data logger/thermometer into the porter as described in this SOP.
- Place a layer of bubble wrap on top of the product then place 1 x small cool pack on top of the bubble wrap.
- Place the polystyrene lid securely onto the system and ensure it is sealed by closing the outer carrying case immediately (ensure that the Velcro fastening is securely sealed).
- Only open the vaccine porter if necessary and remember to re-seal as soon as possible.



How to reset the Thermometers

1. Press the top button once, which should give you either the min or max temp
2. Press it a second time, which should give you either the min or max temp again
3. Press and hold for a third time until you hear a beep. It then needs to go into the fridge to get between 2-8C

Appendix D

Vaccine Porter Cleaning Record v1.0

Date	Time	Vaccine porter No.	Cool packs removed and cleaned (Tick)	Cool packs returned to fridge with cool pack cleaning & refrigeration form attached (Tick)	Polystyrene lid/inner and carry case cleaned (Tick)	Unit is undamaged and suitable for re-use. (Tick)	Vaccine porter rotated into stock (Tick)	Sign