

## Roles, Responsibilities and Training - Vaccine Management in Vaccination Centres and in Community Settings

### Standard Operating Procedure.

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<b>Author:</b>	Senior Pharmacy Technician	
<b>Document Owner:</b>	Chief Pharmacist	
<b>Accountable Executive:</b>	Medical Director	
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The latest approved version of this document is online.  
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### Version Control:

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3	Transfer of MMT SOP 0147 ATO / Pharmacy Support Staff Duties v3.1 to PTHB template. Significant update with the introduction of sections for each duty, for clarity.	08/04/2024
4	Section 6.2 Supporting Vaccinators. Inclusion of vaccine specific instruction to ensure that Covid vaccine sits at room temperature for a defined length of time before administration.	18/06/2024
5	<ul style="list-style-type: none"> <li>• Amendment to SOP title</li> <li>• Removal of reference to pharmacy folders – not longer in use.</li> <li>• Introduction – clarification around staff groups</li> <li>• Responsibilities – minor updates and rewording</li> <li>• Section 6 – Heading -Pharmacy Support Duties changed to Handling Vaccine</li> <li>• Section 6 – reference to pharmacy support removed, replaced with 'named person assigned to pharmacy area'.</li> <li>• Section 6: taking anaphylaxis kits into the community; addition of returning anaphylaxis kits to base</li> <li>• Section 6.3. Refrigerators/Cold Chain -Fridge data logger download- changed from 56 days to weekly. Removal of reference to SD cards.</li> <li>• Section 7 – Training. Clarification of responsibilities and training requirements for different staff groups</li> </ul>	29/05/2025

## Engagement & Consultation

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

Role / Designation
Nikki Mathers, Senior Pharmacy Technician, Immunisation/Vaccination, Therapies & Pharmacy Stores

### Circulated to the following for Consultation

Date	Role / Designation
26/02/2024	Chief Pharmacist
	Senior Clinical Lead Nurse, Immunisation & Vaccination
	Head of Service: Public Health Programmes & Projects
	Lead Nurse, Clinical Supervisor & Vaccination Centre Manager, Immunisation & Vaccination (South)
	Lead Nurse & Clinical Supervisor (North)
12/05/2025	Senior Clinical Lead Nurse, Immunisation & Vaccination Service
	Deputy Clinical Lead, Immunisation & Vaccination Service
	Lead Nurse & Clinical Supervisors: Immunisation & Vaccination.
	Head of Service, Community Pharmacy Service
29/05/2025	Vaccination Programme Operational Development Group for update approval

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## **1 Introduction**

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

Staff (registered and unregistered e.g. Health Care Support Workers (HCSW) Immunisers) in Vaccination Centres (VCs) support this and are integral members of the vaccination team. Staff responsible for the day-to-day management of vaccine are defined as Healthcare Support Workers (HCSW) Immunisers. Registrants also contribute to vaccine management and act as supervisors to their HCSW Immuniser colleagues. Both unregistered and registered staff provide a core vaccine management service in accordance with professional standards, medicines/vaccine standards and legislation.

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

This SOP clearly outlines the specific duties and training requirements of VC staff within VCs and other community settings to ensure the safe and secure management of vaccine and maintenance of the cold chain.

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

It is mandatory that all staff members read the SOPs listed in the essential reading section of this SOP.

It is mandatory for all unregistered staff (HCSW Immunisers) undertaking vaccine management duties in VCs to be trained and signed off as competent in all aspects of vaccine management/cold chain maintenance and to undertake all other training required for the role e.g., level 2 stock management course (GPhC accredited) (see section 7, Training for details)

It is mandatory for all registered staff to have a general underpinning knowledge of basic medicines legislation and to be able to supervise their HCSW Immuniser colleagues, where required in safe management of vaccine (see section 7. Training for details)

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

## 2. Objective

- To clearly outline the duties and training required of VC staff in accordance with professional standards and medicines legislation to support PTHB VC vaccination programmes.

## 3. Essential Reading

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

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

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

## 4. Definitions

- **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 to provide information about the duration of temperature excursions. Data loggers are frequently placed in medicines refrigerators and in vaccine porters during transportation.

- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **HCSW** - Health Care Support Worker
- **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.
- **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.

## 5. Roles / Responsibilities

### 5.1 Head of Service, Public Health Programmes and Projects

The Service Lead must:

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

### 5.2 Senior Clinical Lead Nurse / VC Lead Nurse

- The senior clinical lead nurse / VC lead nurse, in collaboration with the senior pharmacy technician for immunisation / vaccination, and pharmacy stores, is responsible for ensuring that all appropriate staff for whom they have responsibility (e.g., anyone who handles vaccines in VCs / community settings) are trained and competent in vaccine management, have undertaken all other necessary training e.g., cold chain training and

have read, understood, and adhere to the standards in this SOP.

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

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

### **5.4 Other Staff (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 vaccine management related SOPs to support the duties outlined in this SOP and must date the SOP log attached to each SOP when read (see section 3).

## **6. Managing Vaccine**

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

- Liaise with the senior pharmacy technician in relation to all vaccine stock management operational duties and training requirements.

- Refer clinical queries to VC clinical lead or where appropriate, the senior pharmacy technician.

## **6.1 Vaccine Storage Area**

**(Please read section 6 in conjunction with MMP 429 Safe & Secure Stock Management, Handling and Preparation of Vaccines in PTHB VCs and other Community Settings)**

With support from the senior pharmacy technician, a named person must be assigned to cover the following activities:

- Maintaining the vaccine storage area e.g. keeping the area free from clutter and organizing all consumables/equipment neatly.
- Regular sanitising of the vaccine storage area and equipment e.g. surfaces, high touch areas e.g. fridge handles, vaccine trays.
- Managing the VC anaphylaxis kit e.g. ensuring that it is locked away in the medicine's cupboard when not in use, ensuring that it is kept in a safe location during vaccination sessions and that staff are aware of the location of the kit.
- Performing regular expiry checks of the contents of the anaphylaxis kit (black box) and informing the senior pharmacy technician in advance of items expiring.
- Managing the small supply of VC anaphylaxis kits for use in community settings (white cartons) e.g. for outreach clinics and ensuring that these kits are not left unattended during vaccination sessions.
- Ensuring that anaphylaxis kits taken from VCs into community settings are returned to base and locked in the medicine's cupboard at the end of the day.
- Performing regular expiry checks of the contents of the anaphylaxis kits (white cartons) for use in community settings and informing the senior pharmacy technician in advance of items expiring.
- Informing the senior pharmacy technician when stock levels of syringes in the VCs drop to 20 boxes (2000 syringes).
- Managing Patient Information Leaflets (PILs) and ensuring that the correct PILs are available for admin staff to hand out to patients for the vaccine in use.
- Performing oxygen cylinder and mask checks (see appendix A)
- Managing vaccine handout toward the end of the day in collaboration with the admin team and the clinical lead to avoid unnecessary waste.
- Preparing vaccine trays in readiness for the next day.
- Holding the pharmacy key throughout a shift (for fridge and medicines cupboard).

- Supporting training of new staff in vaccine management with support from the senior pharmacy technician and/or the pharmacy store pharmacy technician.
- Responding to pharmaceutical incidents e.g. product re-call, with support from the senior pharmacy technician and /or the pharmacy store pharmacy technician.

## **6.2 Supporting Vaccinators**

With support from the senior pharmacy technician the named person assigned to vaccine management is responsible for:

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

## **6.3 Refrigerators / Cold Chain**

With support from the senior pharmacy technician the named person assigned to vaccine management is responsible for:

- Monitoring fridge temperatures, re-setting and recording on the Welsh Immunisation System (WIS), twice daily.
- Ensuring that vaccine fridges are locked when not in use.

- Ensuring that Labcold vaccine carriers are not left unattended when in use at outreach clinics.
- The swift transfer of vaccine deliveries from +2°C - +8°C to the VC refrigerator to ensure maintenance of the cold chain.
- Ensuring that when fridges are in use, the fridge door/vaccine porter lid e.g. at outreach clinics, is opened for the absolute minimum amount of time.
- Ensuring that vaccine porter lids e.g. Helapet and Labcold vaccine carriers are closed securely after opening to ensure that the cold chain is maintained.
- Ensuring that the fridges are not overloaded with stock, to allow air to circulate freely.
- Responding to and reporting temperature excursions immediately to the clinical lead and the senior pharmacy technician and/or pharmacy stores pharmacy technician. If the senior technician / pharmacy stores pharmacy technician is unavailable, contact the Medicines Management Team immediately, for advice:  
[info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)
- Following the procedure for quarantining stock (see essential reading list, section 3)
- Management of data loggers e.g., downloading data and re-setting. Fridge data loggers should be downloaded once weekly (at the end of the week), or sooner if a fridge temperature excursion occurs. Vaccine porter data loggers must be downloaded, analysed and reset after every use. Data logger downloads must be saved in the relevant file in the Vaccination Team Teams Channel. Access here: [General](#)
- Ensuring that there are spare replacement batteries in the VC for refrigerators.
- Responding to fridge alarms quickly and efficiently.
- Checking that fridges and other equipment e.g. Labcold™ vaccine carriers, data loggers are being used within their calibration period (date of next calibration is located on a sticker on the outside of the fridge/equipment).
- Informing the MMT immediately if the fridge does not seem to be operating efficiently:  
[info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)
- Cleaning vaccine refrigerators (defrosting where necessary) every month and Labcold portable vaccine carriers/Helapet vaccine porters/cool packs after every use.

#### **6.4 Stock**

With support from the senior pharmacy technician, the named person assigned to vaccine management is responsible for:

- Monitoring stock levels and recording on WIS twice daily.
- Reporting stock levels, batch numbers and expiry dates to senior technician once weekly.
- Receipting stock onto WIS.
- Ensuring stock is rotated so that shortest dated stock is at the front of the fridge to be used first.
- Monitoring vaccine expiry dates to ensure that waste is avoided.
- Segregating different vaccines on separate shelves in the fridge to avoid errors in choosing the wrong vaccine.
- Ensuring that fridges are not overstocked e.g. air is able to circulate freely and that the fan / probes are not obstructed.
- Preparation of vaccine for transfer to community settings and entering transfer details onto the stock management Excel spreadsheet.
- Managing stock returned from community settings e.g., care homes/outreach, to ensure that the cold chain can be assured before returning to stock (e.g., analyse the data logger download and save in the relevant file on the VC Teams channel).
- Indicating with a cross and date on the vaccine carton when vaccine is returned to the VC fridge from community settings. Inform the senior technician immediately if any temperature excursions (for any length of time) are evident from the data download.
- Managing quarantined stock e.g., completing quarantine forms, responding to recommended outcomes from pharmacy store staff following investigation into quarantined stock. See essential reading list, section 3.
- Responding to pharmaceutical incidents. See essential reading list, section 3.
- Entering vaccine stock wastage onto WIS.
- Using the stock management Excel spreadsheet for vaccines not supported by WIS e.g. MMR vaccine.
- Managing vaccine transfers for community settings e.g. for care homes, outreach. Raise a reference number and complete the VC Order Processing Spreadsheet located in the Pharmacy Teams channel. Access here: [General](#) See also MMP 447 Vaccination Team/PS Team Stock Management Systems

### **6.5 Vaccine Porters – Helapet (also see essential reading list, section 3)**

With support from the senior pharmacy technician, the named person assigned to vaccine management is responsible for:

- Managing VC Helapet vaccine porters and cool packs e.g., ensuring excess VC Helapet vaccine porters/cool packs are returned to pharmacy stores and that VC Helapet vaccine porters and cool packs are cleaned after each use.
- Ensuring that cool packs are cooled in the fridge for 24 hours before re-use and the relevant paperwork is used to indicate when the cool packs will be next ready for re-use.
- Ensuring Helapet vaccine porters are loaded correctly e.g., the correct number and size of cool packs are chosen for the vaccine porter in use and that the vaccine porter is lined with bubble wrap prior to filling with vaccine.
- Ensuring a data logger has been reset and is placed in the Helapet vaccine porter with the vaccine before it leaves the VC.
- Ensuring data loggers are placed in any spare, empty Helapet vaccine carriers that may be transferred into community settings e.g., for emergency use.
- Management of data loggers e.g., downloading data and re-setting the data logger after use. Helapet vaccine porter data loggers must be downloaded after every use, analysed for cold chain assurance and the data downloaded and saved in the relevant file in the VC Teams channel - [Scanned Docs Scanned Docs](#)
- Indicating with a cross and date on the vaccine carton when vaccine is returned to the VC fridge from community settings. Inform the senior technician immediately if any temperature excursions (for any length of time) are evident from the data download.

## **6.6 VC Helapet vaccine porters/cool packs stock levels**

With support from the senior pharmacy technician, the named person assigned to vaccine management is responsible for:

- Maintaining 2 large vaccine porters and 24 large cool packs in the VC in case of emergencies (e.g., power failure). Each centre should also keep one medium vaccine porter and 28 small cool packs (for ad hoc use in the community) and one small vaccine porter and 12 small cool packs (for ad hoc use in the community). In total:
  - 2 large Helapet vaccine porters
  - 1 medium Helapet vaccine porter
  - 1 small Helapet vaccine porter
  - 24 large cool packs
  - 40 small cool packs

N.B. These quantities can be increased during busier periods or decreased during quieter periods.

- Do not stack cool packs more than 3 high in the refrigerator.

## **6.7 Vaccine Porters - Labcold™**

With support from the senior pharmacy technician, the named person assigned to vaccine management is responsible for:

- Managing Labcold™ Portable Vaccine Carriers e.g., ensuring that they are plugged in, and that the temperature has stabilised between +2°C - +8°C before packing with vaccine.
- Ensuring a data logger has been reset and is placed inside the Labcold™ Portable Vaccine Carrier with the vaccine before it leaves the VC.
- Ensuring that the member of staff transferring vaccine from the VC into a community setting are aware that the Labcold™ Portable Vaccine Carrier must be plugged into the vehicle AV socket. See MMP 428 Use of Labcold™ Portable Vaccine Carriers.
- Management of data loggers e.g., downloading data and re-setting after use. Data loggers used with Labcold™ Portable Vaccine Carriers must be downloaded after every use, analysed for cold chain assurance and the data downloaded and saved in the relevant file - [Scanned Docs](#)
- Indicating with a cross and date on the vaccine carton when vaccine is returned to the VC fridge from community settings. Inform the senior technician immediately if any temperature excursions (for any length of time) are evident from the data download.
- Ensuring that Labcold™ Portable Vaccine Carriers are cleaned (with Clenil wipes) after use and are stored safely and securely to avoid damage to the unit.

**NB. There is no requirement to use cool packs with Labcold™ Portable Vaccine Carriers. Bubble wrap may be used to ensure that vaccine is safely secured and does not move during transport e.g. to pack 'dead space' within the unit.**

## **7. Training**

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

Non-Registrants (HCSW Immunisers)

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

HCSW Immunisers - The following training must be completed:

- New starters must work alongside a trained and competent member of the VC team for a period of time to familiarise themselves with the principles of vaccine management and associated practical duties, prior to competencies being signed off. This time may vary between individuals, according to experience.
- Following adequate training and where the individual feels confident and competent to undertake the practical duties associated with vaccine management with minimum supervision, competencies can be signed off; either by trained and competent VC pharmacy support staff e.g., GPhC accredited staff member (HCSW Immuniser) or by the senior pharmacy technician / pharmacy stores pharmacy technician. Competency sign off sheets can be accessed here: [Competency Checklists Vaccine Management](#)
- The signed competency sheet must be forwarded to Nikki Mathers via [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk) and the newly trained member of staff must keep the original copy in their training file.

## **Registrants**

Registrants are responsible for identifying their own training needs and will be supported by the senior pharmacy technician / pharmacy stores pharmacy technician:

- Registrants are accountable for their own actions and must exercise professional judgement in vaccine management and administration in accordance with standards set by their professional body and in accordance with medicines legislation. Registrants must be able to supervise their HCSW Immuniser colleagues in safe management of vaccine. The senior pharmacy technician and/or the pharmacy store pharmacy technician can provide support on any vaccine management training needs identified by individual clinicians, on request.
- Registrants must be proficient in the practical elements necessary to ensure the safe and secure management of vaccine in VCs and in community settings:
  - Taking and recording fridge temperatures, re-setting the fridge temperature

- Use data loggers e.g. re-setting, downloading, analysing, saving in relevant VC Teams folder.
  - Use of WIS e.g. fridge/stock monitoring/recording waste
  - Use of vaccine porters including Labcold™ portable vaccine carriers. All new starters must sign the competency sheet once training in Labcold™ portable vaccine carrier use has been completed (access here: [Competency Checklists Vaccine Management](#))
  - Maintaining the vaccine stock management Excel spreadsheet (access here: [VC VACCINE RECORD OUTREACH CARE HOMES etc](#))
  - Good understanding of stock management e.g. how to store vaccine correctly, stock rotation/expiry date checking
  - Managing waste (e.g., minimizing waste toward the end of a vaccination session)
- All non-registrants (HCSW Immunisers) and registered staff are responsible for ensuring that training records relating to vaccine management are up to date e.g., reading SOPs, including updates (and signing to confirm that the SOP has been read – sheet attached to the back of each SOP), use of Labcold™ portable vaccine carriers, data logger training etc., including any other training which may be necessary to ensure robust vaccine management.

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

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

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

All staff handling vaccine in VCs and community settings must be familiar with Good Distribution Practice (GDP). GDP training is undertaken individually in the form of a PowerPoint presentation and is certificated 'in-house'. This training must be refreshed annually. For information on how to access GDP training contact Nikki Mathers via [info.medicinesmanagement.powys@wales.nhs.uk](mailto:info.medicinesmanagement.powys@wales.nhs.uk)

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

- The PTHB Management of Refrigerated Medicines SharePoint page:  
[Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents \(sharepoint.com\)](#). This

SharePoint page can be accessed by all PTHB staff involved in the management of the cold chain. All documentation referred to in PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines / Vaccines, can be accessed via this folder and via links throughout the SOP.

VC Pharmacy Teams channel.

This channel is for VC staff only and contains documentation/vaccine management logs etc., specific to vaccine management in VCs and community settings. Access here: [General](#)

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

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

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

## **9. References**

PTHB Vaccination Centre SOPs

[https://nhswales365.sharepoint.com/:f:/r/sites/POW\\_MVCPharmacyTeam/Shared%20Documents/General/Standard%20Operating%20Procedures%20from%20April%202023?csf=1&web=1&e=uiqGhE](https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/Standard%20Operating%20Procedures%20from%20April%202023?csf=1&web=1&e=uiqGhE)

## Appendix A Checking Oxygen Cylinders

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



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

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

