Cleaning / Defrosting Powys Teaching Health Board Medicines / Vaccines Refrigerators

Standard Operating Procedure

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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 - Pharmacy Vaccination Centre SOP 0152 Cleaning / Defrosting Vaccine Refrigerators v1.1	27/01/2023
2	Version updated and transferred onto PTHB SOP template for PTHB wide dissemination. Updates include: • Clear reference to responsibilities • Training section • Essential reading section	08/04/2024

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

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

Circulated to the following for Consultation

Date	Role / Designation
12/02/2024	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)
	Lead Nurses & Clinical Supervisor (South)
	Assistant Head of Public Health Nursing, Women and Children
	Professional Head of Nursing, Specialist Nursing
	Consultant Nurse, Occupational Health
	Head of Community Services, Pharmacy
	District Nurse Team Lead

1 Introduction

Medical grade refrigerators are essential for storing vaccines and medicines properly to maintain temperatures within the manufacturers' recommended range, typically +2°C to +8°C. They come with a range of features to ensure correct storage, including accurate temperature controls, alarms to alert users to temperature changes and locks to keep the medicines safe.

Medical grade refrigerators need to be kept hygienic if they are to be used for storing medicines/vaccines. Regular cleaning and defrosting (where necessary) are essential to prevent the growth of microbes and to ensure the safe storage of medicines/vaccines.

This SOP follows compliance with good practice guidance and manufacturers recommendations.

2. Objective

This SOP clearly describes the processes required to:

- Ensure that trained and competent PTHB staff responsible for the management of refrigerated medicines/vaccines, can safely and routinely clean vaccine refrigerators and where necessary, defrost.
- Ensure that the cold chain is maintained for all medicines/vaccines stored in the refrigerator during the process of cleaning/defrosting.

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.

- **Designated Person** – Senior registered healthcare professional within a ward/department responsible for cold chain management. Responsibilities may be delegated to a deputy, but overall responsibility remains with the designated person.

- **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.

- **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.

- **Temperature deviation/excursion** – any incident where the recorded refrigerator temperature is outside of the recommended range of +2°C to +8°C.

- **Quarantine** - To separate/isolate affected stock from supply chain which must be clearly labelled with 'Quarantined – do not use' and dated.

4. Role / Responsibilities

4.1 Senior Pharmacy Technician Immunisation / Vaccination, Covid Therapies & Pharmacy Stores

The Senior Pharmacy Technician has responsibility for:

- Ensuring that appropriate staff have access to and read and understand this SOP.
- Ensuring that vaccination centre staff are trained in cold chain management.
- Ensuring that PTHB service leads are aware of, implement and review compliance with this SOP within their area of responsibility.
- Arranging regular review to monitor compliance with this procedure at vaccination centres.
- Providing advice on the cleaning and defrosting process.
- Supporting/delegating temperature excursion investigations to appropriate members of the Medicines Management Team

4.2 Service Leads/Designated Person

Service leads/designated persons have responsibility for ensuring that all appropriate staff for whom they have responsibility:

- Have read and understand this SOP.
- Are trained in cold chain management.

Service leads/designated persons must:

- Ensure regular review to monitor compliance with this SOP.
- Have oversight of the cleaning/defrosting process
- Report temperature excursions to the MMT.
- React to temperature excursions i.e. quarantine of stock.

4.3 Other Staff

All staff employed across Powys Teaching Health Board (PTHB) who have access to refrigerated medicines/vaccines and undertake refrigerator cleaning/defrosting duties are responsible for adhering to this SOP, maintaining cold chain training, and reporting and reacting to temperature excursions.

5. Training

All staff using this SOP must be competent to undertake specific tasks within this procedure.

Training can be accessed here:

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

Staff involved in any aspect of management of the cold chain should undertake Good Distribution Practice (GDP) training.

For information on how to access GDP training contact Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk

6. Process - Cleaning

Essential Reading

All staff involved with management of refrigerated medicines/vaccines must read:

- SOP MMP 427 Safe and Secure Management of Refrigerated Medicines/Vaccines
- SOP MMP XXX Use and Management of Vaccine Porters

SOPs can be accessed here:
Management of Refrigerated Medicines Vaccines

6.1 Daily Cleaning

- High touch areas such as door handles should be cleaned daily for high use medicine/vaccine refrigerators such as those used in PTHB Vaccination Centres (VCs), Pharmacy Stores, hospital wards etc.
- Anything visibly dirty or contaminated must be cleaned immediately, regardless of a cleaning schedule, ensuring that the cold chain is always maintained (+2°- +8°C)
- Clenil wipes or similar may be used for the high touch areas.

6.2 Monthly Cleaning

NB. A complete fridge clean (i.e. inside and outside) should be performed monthly. Where possible cleaning should take place during periods of low activity e.g. for vaccination centres cleaning should take place between vaccination campaigns, unless cleaning is urgently necessary. Hospital ward fridge cleaning should take place when stock is at a minimum unless cleaning is urgently necessary.

Work as swiftly as possible to reduce the time that the refrigerator is switched off.

- Check that the temperature of the refrigerator has been maintained between +2°- +8°C.
- Do not transfer stock to a fridge which is under investigation for a temperature excursion.
- Record the minimum/maximum/actual temperature of the refrigerator to be cleaned on the 'Vaccine Fridge Cleaning/Defrosting' log (see appendix A) then reset the temperature.
- Record the minimum/maximum/actual refrigerator temperature of the alternative storage refrigerator identified as a temporary store for the medicines/vaccines from the fridge being cleaned, on the 'Vaccine Fridge Cleaning/Defrosting' log. Reset the fridge temperature. (see appendix A).
- Transfer the contents of the refrigerator to be cleaned to the alternative refrigerator (in vaccination centres, vaccines should be transferred to the cold pack storage refrigerator, providing the cold pack storage refrigerator remains at 50% capacity, if not, some cool packs may be removed temporarily). This will allow the medicines/vaccines to be stored and monitored at the correct temperature whilst cleaning is underway.

- If an alternative refrigerator is not available, refrigerated stock may be temporarily stored in a validated vaccine porter lined with cool packs and bubble wrap. A data logger must be placed inside the vaccine porter to measure the internal temperature during temporary storage of stock. The vaccine porter must be lined with the correct type and quantity of cool packs which have been stored at a temperature of +2C - +8C for at least 24 hours.
- The vaccine porter data logger data must be downloaded when the fridge contents are transferred back to the cleaned refrigerator. This data must be saved and made available at the request of the Medicines Management Team (MMT) (e.g. for audit purposes). NB. Vaccine porters are validated for 8-hours post packing. Ensure that the vaccine porter is clearly labelled with the expiry of the cold chain. Once packed, do not open the vaccine porter lid until the stock is ready to be transferred back into the cleaned fridge.
- When the contents of the refrigerator to be cleaned have been transferred to the alternative refrigerator/vaccine porter, unplug the refrigerator from the mains.
- Remove the shelves and wipe with a weak soapy water solution and leave to dry. Once dry, wipe over with a Clenil wipe.
- Wipe the inside of the refrigerator with a weak soapy water solution and dry with a soft fibreless cloth. Do not use strong detergents or bleach. Never pour water into the unit.
- Wipe the inside a second time with a Clenil wipe.
- Take care with light fittings and ensure that any drain hole at the back of the refrigerator is clear of debris.
- Wipe the door seal with a damp cloth.
- Gently remove dust from the back of the refrigerator. Take care not to damage the pipe.
- Return the cleaned and dried shelves to the refrigerator.
- Plug the cleaned refrigerator socket back into the mains and cool for an hour or until temperature returns to between +2°- +8°C. NB. The refrigerator temperature must reach and stabilise within +2°- +8°C before reloading with stock.
- Once the cleaned refrigerator temperature has reached between 2°- 8°C, reset the fridge temperature. Monitor for 30 minutes before returning stock into the cleaned refrigerator. Once stock has been returned to the cleaned refrigerator, record cleaned refrigerator minimum/maximum/actual temperature on 'Vaccine Fridge Cleaning/Defrosting' log (appendix A) then reset the temperature. Repeat this process after 30 minutes then one hour later.
- Complete refrigerator cleaning/defrosting log fully (see appendix A).

- NB. Ensure that the refrigerator cleaning/defrosting log is kept with the fridge. When logs have been fully completed, save electronically where possible for future reference and audit.

7. Process – Defrosting

Most PTHB refrigerators feature an automatic defrost cycle, however it is recommended that fridges are defrosted manually if there is a visible build-up of ice. This may happen in times of high humidity, if the door has been open for a long time, if the fridge is overstocked, or if the ambient temperature is high.

- Check that the temperature of the refrigerator to be de-frosted has been maintained between +2°- +8°C
- Record the minimum/maximum/actual temperature of the refrigerator to be defrosted on the 'Vaccine Fridge Cleaning/Defrosting' log (see appendix A).
- Record the minimum/maximum/actual refrigerator temperature of the alternative storage refrigerator on 'Vaccine Fridge Cleaning/Defrosting' log (see appendix A).
- Transfer the contents of the refrigerator to be defrosted to the alternative refrigerator (in vaccination centres, vaccines should be transferred to the cold pack storage refrigerator, providing the cold pack storage refrigerator remains at 50% capacity, if not, some cold packs may be temporarily removed). This will allow the medicines/vaccines to be stored and monitored at the correct temperature whilst cleaning is underway.
- A validated vaccine porter is not a suitable alternative to a refrigerator to temporarily store stock while defrosting is underway as the defrosting process is lengthy; up to 12 hours before stock can be transferred back (vaccine porters are validated for 8 hours post packing).
- Contact the MMT for advice if alternative cold storage is not available info.medicinesmanagement.powys@wales.nhs.uk
- When the contents of the refrigerator to be defrosted have been transferred to the alternative refrigerator, unplug the refrigerator to be defrosted from the mains.
- Leave the refrigerator to be defrosted unplugged with the door open for at least 6 hours at room temperature or until any build-up of ice has melted.
- DO NOT USE A SHARP IMPLEMENT TO REMOVE ICE, THIS WILL DAMAGE THE COATING OF THE REFRIGERATOR.
- Remove surplus water, then clean the refrigerator before re-use.
- Remove the shelves and wipe with a weak soapy water solution and leave to dry. Once dry, wipe over with a Clenil wipe.

- Wipe the inside of the refrigerator with a weak soapy water solution and dry with a soft fibreless cloth. Do not use strong detergents or bleach. Never pour water into the unit.
- Wipe the inside a second time with a Clenil wipe.
- Take care with light fittings and ensure that any drain hole at the back of the refrigerator is clear of debris.
- Wipe the door seal with a damp cloth.
- Gently remove dust from the back of the refrigerator. Take care not to damage the pipe.
- Return the cleaned and dried shelves to the refrigerator.
- Wipe the inside of the refrigerator with a Clenil wipe.
- Plug the defrosted and cleaned refrigerator socket back into the mains and leave cooling for **at least 6 hours** before reloading with medicines/vaccines. NB. The refrigerator temperature must reach and stabilise within +2°- +8°C before reloading with stock.
- Once the defrosted and cleaned refrigerator temperature has reached between +2°- +8°C, reset the temperature. Continue to monitor and record the minimum/maximum/actual temperature for a few hours to ensure stability, resetting after each recording.
- Once stock has been returned to the defrosted and cleaned refrigerator, record the refrigerator minimum/maximum/actual temperature on 'Vaccine Fridge Cleaning/Defrosting' log, then reset. Repeat this process one hour later.
- Complete vaccine cleaning/defrosting log and save.

8. Cool Pack Refrigerators

Storing cool packs in fridges containing medicines/vaccines can potentially pose a risk when returning used cleaned cool packs back into the fridge, especially if the cool packs have been left in the empty vaccine porter for more than 8 hours (cold chain will have expired). After 8 hours the cool packs may be warm and could potentially affect the temperature of the fridge (i.e. causing a spike in temperature).

Ideally departments storing large quantities of cool packs and large stock volumes such as vaccination centres and pharmacy stores should have separate fridge(s) for cool pack storage. Other departments such as occupational health, district nursing teams and hospital wards may not have space within their area for extra fridges. This can be mitigated by cleaning and returning cool packs back into the refrigerator before or just after the 8-hour validation has elapsed. A written process should be in place to ensure that this happens.

Refrigerators used for storing cool packs can be cleaned/defrosted by following the processes outlined above. It is unlikely that all cool packs stored in the cool pack fridge can be transferred into the medicines/vaccine fridge during the cleaning/defrosting process, due to large quantities of vaccine stock. However, where there is room, a small quantity of cool packs can be transferred into the medicines/vaccine fridge during cleaning (they will be cold, so will not affect the temperature of the fridge). Ensure that the vaccine fridge is no more than 50% full, inclusive of cool packs. Only transfer the minimum quantity of cool packs into the medicines/vaccine fridge in case of an emergency (i.e., power failure whereby vaccines can be transferred into a validated vaccine porter). Excess cool packs can be stored at ambient temperature until cleaning/defrosting has been completed.

NB. Cool packs that have been stored at ambient temperatures whilst undergoing fridge cleaning/defrosting, must be wiped with Clenil wipes before transferring back into the refrigerator and cooled for 24 hours before re-using.

9. Monitoring Compliance / Audit / Review

Compliance with this SOP will be reviewed during annual pharmacy audits in vaccination centres. All other departments will be audited by the Medicines Management Team during annual audit visits.

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

10. References

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

Labcold Intellicold Operating Instructions Table Of Contents - Labcold IntelliCold Operating Instructions Manual [Page 3] | ManualsLib

Appendix A

FRIDGE CLEANING/ DEFROSTING LOG

Site and Department...

Pre- maintenance				Process	Post- maintenance			
Date	Fridge identity (i.e., vaccine fridge/cool pack fridge)	Fridge to be cleaned/defrosted Temperature pre-clean/defrost (between 2-8C)	Alternative storage fridge Temperature before loading with temporary stock (between 2-8C)	Cleaned/ Defrosted (Please indicate)	Alternative storage fridge Temperature before stock transferred back to original fridge. (between 2-8C)	Cleaned/defrosted fridge Temperature 30 mins post clean/defrost (between 2-8C)	Cleaned/defrosted fridge Temp 1 hour after reloading.	Completed by (sign/date)
		Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:		Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:	
		Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:		Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:	Min: Max: Actual: Time: Temp reset:	
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