**Cold Chain Policy**

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| v1.7 | 27/06/2022 | Sultan Mohamed | Munira Mohamed | Adapted from latest version of Practice index |
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|  |  |  |  |  |

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# Introduction

## Policy statement

This document sets out the requirements for the effective management of the cold chain at Sheerwater Health Centre. This policy supports national guidance regarding the effective maintenance of the cold chain. Nominated staff have additional responsibilities including the effective management of cold chain products.

It is essential that this guidance (and the supporting referenced material) is read to ensure compliance and to maintain product effectiveness. Furthermore, guidance is provided to enable audits to take place to monitor compliance.

This policy should be read in conjunction with the CQC’s [GP Mythbuster 17: Vaccine storage and fridges in GP practices](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters/gp-mythbuster-17-vaccine-storage-fridges-gp-practices).

## Status

The organisation aims to design and implement policies and procedures that meet the diverse needs of our service and workforce, ensuring that none are placed at a disadvantage over others, in accordance with the [Equality Act 2010](https://www.legislation.gov.uk/ukpga/2010/15/contents). Consideration has been given to the impact this policy might have regarding the individual protected characteristics of those to whom it applies.

This document and any procedures contained within it are non-contractual and may be modified or withdrawn at any time. For the avoidance of doubt, it does not form part of your contract of employment. Furthermore, this document applies to all employees of the organisation. Other individuals performing functions in relation to the organisation, such as agency workers, locums and contractors, are encouraged to use it.

# Policy

## Defining the cold chain

The cold chain is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer’s recommended temperature of +2° to + 8°C and protected from light and transferred to a fridge promptly after delivery until the point of administration.

The cold chain process is multifaceted as illustrated in the diagram overleaf and as detailed within [The Green Book Chapter 3](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf).



## Receipt of cold chain products

At Sheerwater Health Centre, the trained member(s) of staff for receiving cold chain products are receptionists. When a delivery arrives at the organisation, the following steps are to be taken to ensure product viability:

* Examine the product(s) for damage/leaks
* Check for order discrepancies (quantity and type)
* Sign for the products only once satisfied and return delivery note to driver
* Update the clinical system to reflect delivery including:
	+ Vaccine/product type and brand
	+ Quantity received
	+ Batch number and expiry date
	+ Date and time of receipt

It is essential that vaccines and other cold chain products are placed into the appropriate fridge upon receipt and not left at room temperature to prevent product degradation.

**2.3 Cold chain product storage**

Vaccines may lose their effectiveness if they are stored outside the recommended temperature range. This may speed up the loss of potency which cannot be reversed. A vaccine may then fail to create the desired immune response and not give protection.

The effectiveness of a vaccine can only be guaranteed if the cold chain process has been maintained and the vaccine stored in accordance with the manufacturer’s guidance, usually between +2° to +8°C.

When storing vaccines in a refrigerator The Green Book advises to:

* Store vaccines in a validated fridge specifically designed for pharmaceutical products. Do not use a domestic fridge
* Only use the fridge to store pharmaceutical products. Do not store food and clinical specimens alongside vaccines
* Maintain the temperature between +2 and +8⁰C. Keep the vaccine fridge secure. It should only be accessible to authorised practice staff. Therefore, keep it locked or in a locked room
* Reduce the possibility of accidentally interrupting the electricity supply. For example, install a switchless socket or clearly label the plug with a cautionary notice: ‘Do not unplug/switch off’
* Use a large enough fridge to allow enough space around the vaccine packages for air to circulate
* Keep the fridge clean with no build-up of ice. Make sure that you:
	+ Follow the manufacturer's servicing recommendations
	+ Calibrate the temperature gauge
	+ Include the fridge in portable appliance testing
	+ Keep vaccines in their original packaging

To optimise efficiency, the following best practice principles should be adhered to:

* Maintain an average fridge temperature of 5°C
* Separate vaccine types within the fridge for ease of identification
* Use labels on the exterior of the fridge to show the location of the vaccine type and expiry date
* Stock rotation must be effective; items with the shortest expiry date should be placed at the front to be used first

## 2.4 Dispensing cold chain products

To maintain cold chain integrity, any cold chain product prescribed to a patient should be dispensed from the fridge and the patient advised as to the necessity of storing the product at the required temperature at home.

## 2.5 Refrigerator specifics

The vaccine fridge should have the sole purpose of storing vaccines. It should not be used for the storage of any other products.

In particular, the fridge should:

* Be clearly identified as a vaccine fridge
* Undergo regular portable appliance testing as detailed within the **PAT and Calibration Testing Policy**
* Have a functioning locking mechanism or be stored in a locked room
* Be clean, sited appropriately and not overfilled
* Have an external maximum – minimum thermometer in place as well as the integrated thermometer
* Undergo a regular servicing programme which is auditable
* Be defrosted (if an icebox is fitted) regularly and this information recorded for audit purposes
* Have an uninterrupted electricity supply (switchless socket) or, where necessary, have the socket clearly labelled ‘vaccine fridge do not turn off’

**2.6 Recording of temperature**

Fridge temperatures should be recorded at least once daily. A log can be found at [Annex A](#_Annex_A_–). The recording process is formed of four stages (the four Rs):

1. **Read:** daily reading of the thermometer’s maximum, minimum and current temperatures at the same time daily during the working week
2. **Record:** recording temperatures in a standard fashion, on a standard form, including signing each entry on the recording sheet (note, this can be done digitally)
3. **Reset:** resetting the thermometer after each reading. The thermometers should also be reset when temperatures have stabilised after periods of high activity
4. **React:** the person making the recording should take action if the temperature falls outside +2° to +8°C and document this action

Ideally, use a second thermometer independent of the integral thermometer in the vaccine fridge. This second reading cross-checks the accuracy of the temperature. It monitors the temperature if the electricity supply to the fridge is interrupted.

Records of fridge temperatures must be retained for a period of 12 months.

**2.7 Data loggers**

A data logger can be used in the vaccine fridge. However, each working day, Sheerwater Health Centre must still:

* Read and record the temperature on the integral fridge thermometer (minimum, maximum and current)
* Reset the minimum/maximum thermometer

This will provide assurance that the fridge contents have been stored correctly and are safe to use.

If a data logger is only checked weekly or monthly, cold chain breaches could be missed. It is then possible vaccines that were stored outside the recommended temperature range were administered.

Data loggers are useful to gain more detailed information about the fridge temperature if there is a cold chain failure, for example a power cut.

**2.8 Actions in the event of a cold chain breach or compromised storage event**

The UKSA has produced a document tilted [Vaccine incident guidance – Responding to errors in vaccine storage, handling and administration](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088780/UKHSA-vaccine-incident-guidance-6-july-2022.pdf) (updated July 2022). This document provides comprehensive guidance on the prompt actions that should be taken.

Furthermore, an algorithm can be found in the UKSA document at Appendix A.

**2.9 Audit**

Conducting a cold chain audit will identify areas of good practice as well as areas for improvement regarding the receipt, storing and monitoring of cold chain items such as vaccines.

A cold chain audit should be conducted at least annually using the pro-forma found at [Annex B](#_Annex_B_–).

**2.10 Promoting best practice**

A poster to promote best practice is available to order using this [link](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294388/Keep-your-vaccines-healthy-poster-March2014.pdf).

# Storage of medicines within an organisation

**3.1 Requirement**

Medicines within the organisation are required to be stored at the correct temperatures and not denatured.

Further reading can be sought from the Royal Pharmaceutical Society guidance titled [Professional guidance on the safe and secure handling of medicines](https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines).

**3.2 Process**

The following process is to be established:

1. On a daily basis, the thermometer within [insert location] is to be checked with readings taken for the minimum, maximum and current temperatures since these was last recorded. The thermometer is to then be reset by [pressing and holding the ‘reset’ button until the display flashes or enter process here]
2. As required, the temperature should be rechecked in an hour to ensure that the required heat has been met
3. All actions are to be recorded upon the medicines store temperature check form at [Annex C](#_Annex_C_–). Any remedial action is also to be logged
4. All check forms are to be kept for a period of 12 months for future reference and evidence of compliance
5. The maximum room temperature of the storage location should not exceed 25°c. Ideally, the temperature should be set lower to allow for warmer days where there is an increase in the ambient temperature
6. Should the ambient temperature be nearing 25°c, action must be taken to cool the area such as using fans, increasing the output of the air conditioning or opening/closing windows and doors. In these circumstances, the temperature should be monitored closely until the temperature has reduced.
7. Should temperatures exceed, or be found to read higher than 25°c, then Nine Taylor (Practice Manager) should be informed immediately so that further action can be taken if needed. All actions are to be recorded on the data sheet.

**3.3 Risk assessment**

To promote compliance and for all staff within the organisation to understand the associated risks, a risk assessment has been completed considering the following:

* New staff
* Busier than normal times
* When the practice is closed, especially for longer than normal periods
* Multiple tasking and/or interruptions
* Weather fluctuations including hot days or stormy conditions
* Power cuts

Supporting guidance on managing risks can be found in the **Risk Assessment Guidance Document.**

# Summary

Effective cold chain management ensures that products are stored safely and securely and remain effective for use whilst minimising the risk of waste at Sheerwater Health Centre.

Staff with additional responsibilities for cold chain management must continually monitor processes to ensure optimal efficiency. Safeguarding the processes and products will safeguard the patient.

# Annex A – Fridge temperature record

**[Insert organisation name] [Insert fridge reference and location]**

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**TEMPERATURE RECORD FOR THE MONTH OF [month] [year]**

# Annex B – Cold chain audit template

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| --- | --- | --- | --- | --- |
| **Criteria** | **Audit result** | **Required actions** | **Target date** | **Date complete** |
| **Policy and procedure** | Yes  | No | N/A |  |  |  |
| Does the practice have an up-to-date cold chain policy (reviewed within the last two years) that is accessible to all staff? |  |  |  |  |  |  |
| Have all staff handling vaccines, from receipt to administration, been trained to follow policies to ensure cold chain compliance? |  |  |  |  |  |  |
| Are there at least two trained people responsible for the ordering, receipt and care of vaccines? |  |  |  |  |  |  |
| **Storage and stock control** |  |  |  |  |  |  |
| Are vaccine stocks monitored prior to ordering? |  |  |  |  |  |  |
| Is there more than four weeks’ supply of vaccine in the refrigerator? |  |  |  |  |  |  |
| Are the expiry dates of vaccines monitored and close to expiry stock clearly labelled? |  |  |  |  |  |  |
| Is stock rotation carried out to ensure shortest expiry dates are used first? |  |  |  |  |  |  |
| Is not more than 66% of the internal volume of the fridge filled? |  |  |  |  |  |  |
| Are items stored away from the back and sides of the fridge and the freezer compartment if it has one? |  |  |  |  |  |  |
| **Receipt of vaccines** |  |  |  |  |  |  |
| Are vaccines checked against the order for discrepancies and leakage or damage before signing for them?  |  |  |  |  |  |  |
| Is there a procedure for recording the date and time at which vaccine types, brands, quantities, batch numbers and expiry dates were received? |  |  |  |  |  |  |
| Are vaccines refrigerated immediately on receipt? |  |  |  |  |  |  |
| **Refrigerator** |  |  |  |  |  |  |
| Is the refrigerator of adequate size to correctly store the volume of vaccines required? |  |  |  |  |  |  |
| Is the refrigerator dedicated to pharmaceutical products only? |  |  |  |  |  |  |
| Is anything other than vaccines stored in the refrigerator? |  |  |  |  |  |  |
| Is the refrigerator either both lockable and locked or in a locked room? |  |  |  |  |  |  |
| Is the electricity supply safe, e.g., switchless plugs or cautionary notices in place to prevent accidental unplugging? |  |  |  |  |  |  |
| Are there contingency arrangements in place in the event of a refrigerator failure or power cut including back up facilities? |  |  |  |  |  |  |
| Are there records of regular servicing, defrosting and cleaning as per the manufacturer’s recommendations? |  |  |  |  |  |  |
| **Temperature monitoring** |  |  |  |  |  |  |
| Is there a named person and deputy responsible for monitoring the fridge? |  |  |  |  |  |  |
| Are procedures in place for *at least* daily recording of temperatures? |  |  |  |  |  |  |
| Is an appropriate recording form used? |  |  |  |  |  |  |
| Are the minimum, maximum and actual temperatures in the refrigerator monitored and recorded and acted upon if required? |  |  |  |  |  |  |
| Is the four R’s process followed? |  |  |  |  |  |  |
| Are thermometers calibrated and serviced annually? |  |  |  |  |  |  |

Date of audit:

Name of person completing audit:

Role of person completing audit:

If there are required actions, is there a plan in place to complete: Yes or No\*

Date actions completed:

Signature:

Print name:

\* delete as applicable

# Annex C – Medicines storage temperature checks

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[Month and year]