

MERSEY CARE NHS TRUST - HOW WE MANAGE COLD CHAIN MEDICINES

MM 21 Procedure for Storage, Ordering, Distribution and Administration of Cold Chain Medicines

- Medicines Management Services aim to ensure that*
- (i) *Service users receive their medicines at times that they need them and in a safe way.*
 - (ii) *Information on medicines is available to staff, service users and their carers*

KEY ISSUES

Procedure and guidelines for staff for Cold-Chain Principles when ordering, distributing and administering Cold-Chain Medicines.

Medicines Management Procedure – MM21
Approved by Drugs and Therapeutics
Committee March 2018
Edited by Mawugbe Gbededo
Version 1.1

For review March 2020

CONTENTS

Section	Page
1 INTRODUCTION	3
2 PURPOSE	3
3 AIM	3
4 DEFINITION	3
5 ROLES AND RESPONSIBILITIES	3
6 PERSONS RESPONSIBLE FOR RECEIPT / STORAGE OF COLD CHAIN MEDICINES	4
7 ORDERING AND MONITORING OF STOCK	4
8 PACKING, ISSUE AND TRANSPORT OF COLD CHAIN MEDICINES	5
9 RECEIPT OF COLD CHAIN MEDICINE WITHIN THE HEALTH CENTRE	5
10 RECOMMENDED TEMPERATURES FOR STORAGE AND TRANSPORT OF COLD CHAIN MEDICINE	5
11 RECOMMENDED COLD CHAIN MEDICINE STORAGE CONDITION	6
12 MAINTAINING COLD CHAIN MEDICINE AT THE RECOMMENDED TEMPERATURE	6
13 USE OF COOL BOX	7
14 DISPOSAL	7
15 ACCIDENTAL AND/OR TEMPORARY DISCONNECTION OF THE ELECTRICAL SUPPLY	7
16 AUDIT	9
17 Appendix 1 –summary document	10

1. INTRODUCTION

Cold chain medicines generally need to be stored in a cold chain. This procedure covers issues raised in the NPSA Rapid Response Report on Cold-Chain Medicines storage.

The efficacy and safety of Pharmaceuticals, including cold-chain medicines requiring controlled low temperature storage depends on maintaining temperatures within the manufacturers recommended range, typically 2-8°C. If the storage recommendations are not followed, the efficacy of the cold-chain medicines may be compromised and manufacturers can disclaim responsibility for any apparent failure of the product.

2. PURPOSE

This procedure is to ensure that cold-chain medicine manufacturers' recommendations regarding Storage, Ordering, Distribution and Administration of cold-chain medicines are adhered to, in order to protect individual service user/patient care.

This procedure applies to staff involved in the ordering, storage and administration of cold-chain medicines. The health centre may only hold cold-chain medicines in stock as approved by the Pharmacist.

Throughout this procedure, references to cold-chain medicines also refer to the appropriate diluents for those cold-chain medicines, needing diluents.

3. AIM

To provide staff with standards for maintaining the cold-chain medicines and thereby reduce the risk of compromising the quality and safety of the vaccines administered to service users/patients.

4. DEFINITION

Cold-Chain Medicines are medicinal substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage. The efficacy of cold-chain medicines depends on maintaining the cold-chain.

The cold chain can be defined as the storage and transport of pharmaceuticals requiring controlled low temperature storage between 2-8°C from manufacture until the point of administration to a service user/patient.

5. ROLES AND RESPONSIBILITIES

As this is a sub procedure from SD12 please refer to roles and responsibilities within SD12

6. NURSING STAFF RESPONSIBLE FOR RECEIPT/STORAGE OF COLD-CHAIN MEDICINES

The nursing staff responsible for receipt/storage of cold-chain medicines must be competent in reading and resetting a maximum/minimum thermometer or other appropriate temperature recording device and in recognising the importance of maintaining the cold-chain.

7. ORDERING AND MONITORING OF STOCK

The nursing staff, to avoid over ordering or stockpiling, should monitor cold-chain medicine stock. Cold-Chain Medicine is issued to a clinical area on receipt of requisition or prescription

Best practice is to order smaller quantities on a regular, scheduled basis. Excess stock may:

- Increase the risk of administering out-of-date cold-chain medicines.
- Increase wastage and cost of disposal by incineration.
- Increase the dangers of over-packed refrigerators leading to poor airflow, potential freezing and poor stock rotation.
- Increase the cost of replacement stocks if the refrigerator fails.

Cold-Chain medicines should be stored within the refrigerator so that those with shorter expiry dates are used first. Cold-Chain Medicines must never be used when past their expiry date.

Any out-of-date stock should be labelled clearly, removed from the refrigerator and destroyed as soon as possible according to the local procedure.

8. PACKING, ISSUE AND TRANSPORT OF COLD-CHAIN MEDICINES

Wherever along the cold-chain medicines are packed, issued or transported, the following principles should be applied:

Orders will be assembled at the Medicines Management Maghull Health Park Pharmacy Department for the Secure and Local Divisions immediately prior to dispatch unless a cold room is available for storage of packed courier bags or cold boxes. If packing occurs at normal room temperature, it should be undertaken so as to minimise the time in which the cold-chain medicine is exposed to such a temperature.

Transport delays should be avoided and orders will be clearly labelled "**Cold-Chain Medicine for Urgent Delivery**".

The driver collecting the cold-chain medicine will be told that the delivery contains cold-chain medicines. Cold-chain medicine deliveries will be packed in a cold-chain bag and must be accompanied by a completed transport form. They will be delivered by Transport to the point of delivery and should be handed to, and signed for by a qualified nurse.

Cold-chain medicines must not be delivered and then be left unattended.

9. RECEIPT OF COLD-CHAIN MEDICINE ORDER WITHIN WARDS AND DEPARTMENTS

Upon receipt by a registered nurse, the cold-chain medicine must be unpacked IMMEDIATELY from the bag. However, they must be kept in their original packaging as they may need to be protected from light. Cold-chain medicines must be immediately placed in the designated refrigerator within the ward / clinic. Cold-chain medicine must not be left at room temperature.

All orders must be checked on receipt for leakage, damage and discrepancies. In the event of a discrepancy the Medicines Management dept should be contacted immediately.

The registered nurse must sign for the delivery.

10. RECOMMENDED TEMPERATURES FOR STORAGE AND TRANSPORT OF COLD-CHAIN MEDS

The manufacturer's recommendations on storage temperatures, between 2-8°C must be observed when transporting cold-chain medicines.

Do not freeze as this may cause increased reactogenicity and loss of potency rendering the cold-chain medicines useless. It can also cause hairline cracks in the container, leading to contamination of the contents.

Cold-chain medicines must always be protected against light.

11. RECOMMENDED COLD CHAIN MEDICINES STORAGE CONDITIONS

Some cold-chain medicines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Cold-chain medicines should never be left unattended at outlying clinics/departments.

The fridge must be a specialized refrigerator for storage of pharmaceuticals. Ordinary domestic fridges must not be used.

All fridges must be lockable or in a locked room, with restricted public access.

There must be enough space for air to circulate freely around the back of the fridge.

The fridge plug must be secured to avoid disconnection (i.e. *wired directly into the socket*) and labelled 'do not switch off'.

The fridge must be monitored with a digital maximum/minimum thermometer, which also records the actual temperature. Ideally, this will be the manufacturer's in-built fridge thermometer.

The fridge must be regularly cleaned and defrosted according to the manufacturer's instructions.

If the fridge is not self-defrosting, the cold chain must be maintained whilst defrosting the fridge by moving all stock to another fridge or validated cool box.

The contents should be evenly distributed within the fridge to allow air to circulate.

Stock must be rotated according to expiry date and the older stock positioned at the front of the fridge to use first.

Out of date stock must be returned to the Medicines Management department.

12. MAINTAINING COLD-CHAIN MEDICINES AT THE RECOMMENDED TEMPERATURES.

A named nurse and named deputy must be responsible for monitoring the fridge.

The following must be monitored and recorded each working day:

- The **actual** temperature
- The **maximum** temperature
- The **minimum** temperature
- The **date** on which the refrigerator was last defrosted should also be recorded where it is not fitted with an automatic defrosting mechanism.

The thermometer **must be reset** after each reading is made. Follow the manufacturer's instructions for resetting the thermometer.

Any refrigerator temperature falling outside the limits of 2-8°C where the cold-chain medicines are stored must be reported to the Pharmacist/Technician and to the Medicines Management team, Maghull Health Park.

13. USE OF COOL BOX

Cool packs (*that have been stored at 2-8°C for a minimum of 5 hours*) should be placed around the cold-chain medicines, and spaces filled with other appropriate packaging material.

Commercial (*not domestic*) cool packs should be used, and it is vital the manufacturer's instructions are followed regarding their use.

Any spaces within the cool box load should be filled with appropriate insulating material. This will prevent temperature variations due to shifting of the load within the box, either from the shipment or disturbance on delivery.

Cool boxes should only be packed immediately prior to transporting. Any spaces must be filled with appropriate insulating material to prevent temperature variations due to shifting of the load within the box.

Only keep cold-chain medicines out of refrigeration for recommended periods, as outlined by the cold-chain manufacturer.

14. DISPOSAL

Intact and unopened cold-chain medicines which are no longer required must be returned in a cool box to the dispensing Pharmacy Department at Medicine Management Building, Maghull Health Park, Ashworth Hospital.

Unopened ampoules, vials and diluents that have been removed from the refrigerator should be placed in a sharps container for incineration.

Time expired ampoules of cold-chain medicines should be discarded into designated sharps container for incineration.

15. ACCIDENTAL AND/OR TEMPORARY DISCONNECTION OF THE ELECTRICITY SUPPLY

Note the refrigerator current temperature, maximum and minimum temperatures.

If within the range of 2-8°C: Reconnect the power supply, no further action is required.

If outside the range of 2-8°C: Cold-chain medicines which have been exposed to temperatures outside the range of 2-8°C **MUST NOT BE USED** unless specifically authorised by a Pharmacist.

Pharmacy Medicines Information must be contacted for advice on 0151 250 6011. They will need to know the cold-chain medicine name, manufacturer and timescale at which the cold-chain medicine has been left out of

refrigeration. Pharmacy will check UKMI fridge data base in the first instance and then contact the manufacturer for further guidance, if necessary. Complete a Ulysses or DATIX report.

Reconnect the power supply, taking note of the time at which the supply was reconnected.

Try to establish how long the cold-chain medicine may have been outside the required range of temperatures, check for any evidence of previous exposure of the cold-chain medicine to breaks in the cold-chain and establish the appropriate number and types of cold-chain medicines including any which are marked 'USE FIRST', currently in stock.

If advised to use the cold-chain medicine which has been exposed to higher than normal storage temperatures, then these stocks should be marked 'USE FIRST' and should be used before any other cold-chain medicines stock is used.

REFRIGERATION BREAKDOWN OR MALFUNCTION

Note the refrigerator current temperatures, maximum and minimum temperatures.

- **If inside the range of 2-8°C**

Transfer the items to another refrigerator if possible, keeping them separate from the contents of the other refrigerator.

Make arrangements for the urgent repair or replacement of the refrigerator.

- **If outside of the range 2-8°C**

Transfer the items to another refrigerator if possible, keeping them separate from the contents of the other refrigerator.

If transfer to another refrigerator is not possible, keep the door of the malfunctioning refrigerator closed.

Try to establish how long the cold-chain medicines may have been outside the required range of temperatures, check for any evidence of previous exposure of the cold-chain medicines to breaks in the cold-chain, and establish the approximate number and types of cold-chain medicines, including any which are marked 'USE FIRST', currently in stock. Contact the following for advice about the use and/or disposal of the cold-chain medicines.

- i) Trust Ward Pharmacist
- ii) Pharmacy Medicines Information must be contacted for advice on 0151 250 6011.

If advised to use a cold-chain medicine which has been exposed to higher than normal storage temperatures, then these stocks should be marked '**USE FIRST**' and should be used before any other cold-chain medicine stock is used.

16. AUDIT

Refrigerator storage is monitored and audit as part of the routine Safe and Secure Storage of Medications Audits.

Temperature monitoring and recording of the actual, the maximum and the minimum temperatures on each working day should be done.

Appendix 1

Safe Storage of Vaccines

Vaccines may lose their effectiveness if they become too hot or too cold at any time. Therefore, from the manufacturer to the point of administration, vaccines must be transported and stored at a recommended temperature of +2°C to +8°C to maintain the cold chain.

- Vaccines should be stored at temperatures between +2°C to + 8°C in the original packaging and protected from light. Vaccines must not be frozen.
- Vaccines must be stored in pharmaceutical standard refrigerator that is specifically designed for storing medicines or vaccines.
 - o Ordinary domestic refrigerators must not be used.
 - o Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines.
 - o The fridge must not be overstocked. Allow sufficient space around the vaccine packages for air to circulate.
 - o Vaccines should be kept away from the side and back walls of the refrigerator
- A Trust-approved pharmaceutical grade vaccine carrier and cool packs OR a calibrated portable refrigerator in conjunction with a validated thermometer should be used to transport or temporarily store vaccines. Vaccine packaging should not come into contact with any frozen ice or gel pack. For advice on vaccine carriers, contact Pharmacy on 0151-250 6245/6084.
- Arrangements should be in place for back-up facilities to be available in the event of the refrigerator failing or breaking down eg: use vaccine carrier or portable fridge or nearest pharmaceutical fridge.
- The temperatures of the vaccine fridge or vaccine carrier must be monitored at least twice on each working day (at the beginning and end of each session) using a reliable, calibrated temperature monitoring device. Minimum-maximum temperatures should be documented on a chart and the temperatures reset after each reading. During use ensure that the temperatures do not go outside the recommended range.
- Vaccines that have not been stored or transported within the required temperature range of +2°C to + 8°C will no longer comply the terms of the product licence (off-label use).
- Out-of-range storage temperatures require prompt action.

- o Any vaccine exposed to temperatures outside the recommended range of +2°C to + 8°C should be clearly labelled and quarantined but stored in a functional monitored fridge.
 - o Further advice on appropriate action to take may be obtained from Pharmacy on 0151-250 6011.
- Vaccines stocks must be refrigerated immediately once received and must not be left at room temperature.
 - To maintain the cold chain, it is good practice to remove vaccines from the refrigerator as needed, depending on the number of people present at the session.
 - o Avoid removing too many vaccines (e.g. whole boxes) at the beginning of a session to avoid exposure to temperatures above +8°C
 - o Prepare vaccines only when ready to administer them.
 - For vaccination of Trust staff where a fridge is not available, ensure a portable fridge or Trust-approved vaccine carrier equipped with a temperature monitoring device is used. Remaining vaccines should be marked clearly and returned to the vaccine refrigerator as soon as possible after each session.
 - o Providing there is evidence from the temperature monitoring that the cold chain has been maintained, these marked vaccines should be used at the earliest opportunity.
 - o If the cold chain has not been maintained or the vaccines have been kept at room temperature, ring Pharmacy on 0151-250 6011 for further advice on appropriate action to take.

