

MERSEY CARE NHS TRUST – HOW WE MANAGE MEDICINES

MM 21 Procedure for Storage, Ordering, Distribution and Administration of Vaccines (Cold Chain)

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 vaccines

Medicines Management Procedure – MM21
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CONTENTS

SECTION		PAGE NO
1	INTRODUCTION	4
2	PURPOSE	4
3	AIM	4
4	DEFINITION	4
5	ROLES AND RESPONSIBILITIES	5
6	PERSONS RESPONSIBLE FOR RECEIPT/STORAGE OF VACCINES	6
7	ORDERING AND MONITORING OF STOCK	6
8	PACKING, ISSUE AND TRANSPORT OF VACCINES	6
9	RECEIPT OF VACCINE ORDER WITHIN THE HEALTH CENTRE	7
10	RECOMMENDED TEMPERATURES FOR STORAGE AND TRANSPORT OF VACCINES	7
11	RECOMMENDED VACCINE STORAGE CONDITIONS	7
12	MAINTAINING VACCINES AT THE RECOMMENDED TEMPERATURES	8
13	USE OF COOL BOX	8
14	DISPOSAL	9
15	ACCIDENTAL AND/OR TEMPORARY DISCONNECTION OF THE ELECTRICITY SUPPLY	9
16	AUDIT	10

1. INTRODUCTION

Vaccines generally need to be stored in a cold chain – see Chapter 3 of the [Green Book](#) for further details.

This procedure covers issues raised in the NPSA Rapid Response Report on Vaccine Cold Storage, NPSA/2010/RRR008.

The efficacy and safety of pharmaceuticals, including vaccines, 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 vaccine may be compromised and manufacturers can disclaim responsibility for any apparent failure of the product.

2. PURPOSE

This procedure is to ensure that vaccine manufacturers' recommendations regarding Storage, Ordering, Distribution and Administration of Vaccines (Cold Chain) 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 vaccines. The health centre may only hold vaccines in stock as approved by the Pharmacist.

Throughout this procedure references to vaccines also refers to the appropriate diluents for the vaccines.

3. AIM

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

4. DEFINITION

Vaccines are biological 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 vaccines 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

Chief Executive

The Chief Executive is responsible for ensuring that there are effective arrangements for Infection Prevention and Control Committee (IPC) within the Trust. These arrangements are overseen by the IPC Committee and the Trust Designated Director for (IPC).

An annual infection control programme is supported by and approved by the Trust Board. The Chief Executive ensures that there are direct links from the IPC Committee and Risk and Quality Committees with the Trust.

Trust Medical Director

The Trust Medical Director has delegated responsibility for the co-ordination of IPC arrangements across the Trust. The Director of IPC is accountable directly to the Chief Executive as well as the Board.

Director of Infection Prevention and Control (DIPC)

They are members of the Infection Control Committee and provide guidance and support to the Trust on all infection control matters.

Director of Operations, Clinical Nurse Managers and Ward Managers are responsible for the distribution and implementation of infection control procedures and guidance in services. Ensure that the service user/patient environment is clean in accordance with NHS standards. Ensure that appropriate staff is scheduled to attend induction and mandatory IPC training sessions. It is the responsibility of managers to ensure that appropriate protective equipment is in place on the ward/department.

Infection Prevention and Control Nurse

The Infection Prevention and Control Nurse is responsible for, planning and developing an efficient and effective service across the Trust, which meets with national government targets and service frameworks in relation to infection control. This will involve the prevention, surveillance, investigation and control of infection across the Trust.

The Infection Prevention and Control Nurse (IPCN) is responsible for producing and updating all IPC policies, providing hand hygiene training and control of Health Care Associated Infections (HCAI's) and monitoring compliance in wards and other clinical areas.

6. NURSING STAFF RESPONSIBLE FOR RECEIPT/STORAGE OF VACCINES

The nursing staff responsible for receipt/storage of vaccines 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 vaccine stocks. Vaccines are issued to a clinical area on receipt of a requisition.

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

- Increase the risk of vaccination with out-of-date vaccines.
- Increase wastage and cost of disposal by incineration.

- Increase the dangers of over-packed refrigerators leading to poor air flow, potential freezing and poor stock rotation.
- Increase the cost of replacement stocks if the refrigerator fails.

Vaccine stocks should be stored within the refrigerator so that those with shorter expiry dates are used first. Vaccines 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 VACCINES

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

Orders will be assembled at East Lancashire Hospitals Pharmacy Department for Specialist Learning Disabilities Division and at Mossley Hill Hospital 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 vaccine is exposed to such a temperature.

Transport delays should be avoided and orders will be clearly labelled “**Vaccines for Urgent Delivery**”.

The transport person collecting the vaccines will be told that the delivery contains vaccines. Vaccine deliveries will be packed in a Vaccine Porter and must be accompanied by a completed transport form. They will be delivered by the Transport department to the point of delivery and should be handed to, and signed for, by a qualified nurse.

Vaccines must not be delivered and then be left unattended.

9. RECEIPT OF VACCINE ORDER WITHIN THE HEALTH CENTRE

Upon receipt by a registered nurse the vaccines must be unpacked **IMMEDIATELY** from the portable fridge/Vaccine porter. However, they must be kept in their original packaging, as they may need to be protected from light. Vaccines must be immediately placed in the designated refrigerator within the Health Centre. Vaccines 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 Senior Technician – East Lancashire Hospitals Pharmacy Department will be contacted immediately for the Specialist Learning Disabilities Division and the stores team at Mossley Hill Hospital for the Secure and Local Divisions.

The Registered nurse must sign for the delivery.

10. RECOMMENDED TEMPERATURES FOR STORAGE AND TRANSPORT OF VACCINES

The manufacturer’s recommendations on storage temperatures, between 2–8°C must be observed when transporting vaccines.

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

Vaccines must always be protected against light as they are very sensitive to strong light, and exposure to ultraviolet light will cause loss of potency.

11. RECOMMENDED VACCINE STORAGE CONDITIONS

All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Vaccines 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 Pharmacy stores.

12. MAINTAINING VACCINES 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 vaccines are stored must be reported to the Pharmacist/Technician. East Lancashire Hospitals Pharmacy Department for the Specialist Learning Disabilities Division and to the Pharmacy Department at Maghull for High Secure Services and The Pharmacy Department at Mossley Hill for all other services. .

A validated dedicated vaccine porter must be used for transporting vaccines from the any site and to other treatment areas away from the main site.

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 vaccines, 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 the 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 vaccines out of refrigeration for recommended periods, as outlined by the vaccine manufacturer.

14. DISPOSAL

Intact and unopened vaccines which are no longer required must be returned to the dispensing Pharmacy Department at East Lancashire Hospitals for disposal for the Specialist Learning Disabilities Division. Secure and Local Divisions must follow the guidance in SD12 .

Opened ampoules, vials, unused vaccines and diluents that have been removed from the refrigerator will be placed in a sharps container for incineration.

Time expired ampules of vaccine should be discarded into a 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: Vaccines 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; for Specialist Learning Disabilities Division - RBH 01254 263555 extension 13004. For Local and Secure Division the MI team are available on 0151 250 6011. They will need to know the vaccine name, manufacturer and timescale at which the vaccine 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 vaccines may have been outside the required range of temperatures, check for any evidence of previous exposure of the vaccines to breaks in the cold-chain, and establish the approximate number and types of vaccines, including any which are marked "USE FIRST", currently in stock.

If advised to use a vaccine 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 vaccine stock is used.

REFRIGERATOR BREAKDOWN OR MALFUNCTION

Note the refrigerator current temperature, maximum and minimum temperatures.

- **If inside the range 2-8°C**

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

If transfer to another refrigerator is not possible then keep the door of the malfunctioning refrigerator closed and keep regular checks on the temperature of the 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 vaccines may have been outside the required range of temperatures, check for any evidence of previous exposure of the vaccines to breaks in the cold-chain, and establish the approximate number and type of vaccines, including any which are marked "USE FIRST", currently in stock. Contact one of the following for advice about the use and/or disposal of the vaccine:

- i) Trust Pharmacist
- ii) The Vaccine Manufacturer

If advised to use a vaccine 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 vaccine stock is used.

16. AUDIT

Refrigerated 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

**STAFF AWARENESS AND UPDATING OF TRUST AND DEPARTMENTAL POLICIES
AND PROCEDURES**

I have read and understood the procedure

STAFF NAME	SIGNATURE	DATE