



STORAGE AND HANDLING OF VACCINE AND REFRIGERATED MEDICINES POLICY

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DOCUMENT CONTROL SHEET

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VERSION CONTROL

Version Date	Version no.	Author/Reviewer	Summary of changes
Jan 2012	4	IPCS	Logo changed
Dec 2013	5	ADIPC	Equality & Diversity
Dec 2015	6	ADIPC	Minor changes
Jan 2018	7	Emma Tang	Title change, role & responsibilities, monitoring & audit, temp monitoring sheet, specifications for fridge, thermometer & data logger, covers other refrigerated medicines, temperature monitoring section and sheet
Sept 2020	8	Francoise Price	Minor changes – grammatical and semantics; update references
August 2022	9	Emma Tang	Minor changes, included COVID-19 vaccines, training requirement

EQUALITY AND DIVERSITY IMPACT ASSESSMENT

Impact Assessments must be conducted for:

- All ECCH policies, procedures, protocols and guidelines (clinical and non-clinical)
- Service developments
- Estates and facilities developments

Name of Policy / Procedure / Service	Storage and Handling of Vaccine and Refrigerated Medicines Policy
Manager Leading the Assessment	Emma Tang
Date of Assessment	27.06.2022

INITIAL ASSESSMENT

<p>Q1. Is this a new or existing policy / procedure / service?</p> <p>√ Existing</p>
<p>Q2. Who is the policy / procedure / service aimed at?</p> <p>√ Staff</p>
<p>Q3. Could the policy / procedure / service affect different groups (age, disability, gender, race, ethnic origin, religion or belief, sexual orientation) adversely?</p> <p>√ No</p> <p>If the answer to this question is NO please sign the form as the assessment is complete, if YES, proceed to Stage Two.</p>

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1. INTRODUCTION

For many vaccines and refrigerated medicines e.g., insulin efficacy depends on maintaining the 'cold chain' at every stage from the manufacturer, through delivery and storage, to the recipient.

Cold chain is a term used to describe the cold temperature conditions (2 – 8 °C) 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 range of 2 – 8 °C until the point of administration.

Any refrigerated vaccine or medicine that has been stored outside a temperature of 2 – 8 °C as per its licensing conditions is no longer a licensed product and may be rendered ineffective

Vaccines, and other refrigerated medicines, naturally biodegrade over time and storage outside of the recommended temperature range – including during transport– may speed up this loss of potency, which cannot be reversed. This may result in the vaccine failing to protect the patient or the drug not working as well as resulting in wastage.

Inactivation of vaccines may only come to light when immunised individuals acquire the disease in question. It may then be difficult to demonstrate a clear link between this and previous inadequate storage, distribution, and handling practices.

High standards are necessary and are encouraged by appropriate training of staff involved with immunisation and medicines handling; clear designation of responsibilities to named individuals; the development and implementation of written protocols and continuing regular audit.

2. PURPOSE AND SCOPE

To provide standards to anyone storing and handling vaccines and refrigerated medicines within East Coast Community Healthcare (ECCH) and thereby reducing the risk of compromising the quality and safety of the products administered to their patients.

This policy applies to all staff, whether commissioned, contracted, or directly employed by the ECCH. These staff may work within ECCH premises, patients own homes, or care settings owned by other agencies. Others (GP Practices) may choose to adopt this policy as their own; this should be documented at a suitable meeting as the agreed policy.

This policy applies to all vaccines (include thawed COVID-19 vaccines) and medicines that must be stored refrigerated between 2 – 8 °C.

3. ROLE AND RESPONSIBILITIES

Everyone involved in receipt, storage and handling of refrigerated vaccine and medicines must be trained in the importance of maintaining the cold chain.

It is the responsibility of all department heads/professional leads to ensure that the staff they manage adhere to this policy.

Each site where refrigerated medicines and vaccines are stored must have a trained and designated person responsible for receipt and safe storage of these medicines. This person should identify another trained person to deputise in times of absence.

4. SPECIFICATIONS OF REFRIGERATOR

Ordinary domestic fridges must never be used for storage of medicines or vaccines.

The medicines fridge must be a specialised refrigerator. These are purpose-built and designed with the following features:

- Internal temperatures are regulated by a temperature regulation mechanism, which ensures minimal tolerance for any deviation.
- Air is circulated continuously ensuring the temperature is distributed evenly throughout the fridge.
- The internal temperature is maintained at 2 – 8 °C
- The temperature recovery system works quickly

Steps must be taken to ensure the medicines fridge is not switched off inadvertently. Plugs should be clearly marked with a “Do not switch off” label or other means of preventing them being inadvertently switched off.

Ensure the medicines fridge is placed in a dry, well-ventilated site, away from direct sunlight and heat sources such as radiators. Air should be able to circulate freely on all sides of the refrigerator. Failure to do this may result in overheating of the fridge, especially in very hot weather.

A maintenance contract must be in place to ensure yearly servicing of the medicine’s fridge and calibration of the temperature gauge / thermometer. The refrigerator has regular visual inspection and portable appliance testing (PAT) to ensure it remains safe to use.

5. THERMOMETER AND DATA LOGGER

The medicines fridge must be monitored using a thermometer which measures both the minimum and maximum temperature. Most medicines fridge has integral probe connected to a digital display.

Two maximum/minimum thermometers must be available per medicines fridge. One must be independent of mains power so temperatures can be measured in the event of electricity loss.

Each digital thermometer must be recalibrated annually as part of the maintenance programme.

Where external thermometers are used, the temperature monitoring probe should be suitably housed to simulate packaged products and to minimise fluctuations in temperature caused by air movements. This should be sited in a central location within the medicine’s fridge, preferably between the products - they should not be placed in the door.

Data loggers are small electronic devices that are used to record medicines fridge temperature continuously and can provide a historical record of the temperature. The information can be downloaded to a computer via software supplied. Data loggers will display information about temperature recordings and log the length of time a storage unit has been

operating outside the recommended temperature range. This is especially useful in the event of a cold chain breach when trying to establish how long the fridge temperature may have been compromised.

Please note that minimum/maximum temperatures must still be manually recorded at least once on every working day, ideally at the same time each day, as a timely alert to any breach in the cold chain.

6. SAFE AND SECURE STORAGE

A specialised refrigerator must be dedicated to **vaccines and medicines only**. Food, drink or clinical specimens must not be kept in medicines fridge under any circumstance.

Opening of the refrigerator door should be kept to a minimum in order to maintain a constant temperature.

Do not keep large amounts of vaccine or medicines in the medicines fridge as this can lead to inadequate air flow and potential freezing. Medicines must not be in contact with internal surfaces (including the floor of the fridge) to allow adequate airflow. No more than two to four weeks supply of vaccine or medicines should be kept at any time. Best practice is to order small quantities on a regular, scheduled basis.

It is recommended that an additional vaccine storage refrigerator is available to cover periods of particularly high usage (e.g., the influenza immunisation period).

The medicines fridge must be locked at all times when not in use. Staff should be aware of key storage and access.

Vaccines and refrigerated medicines should be placed, as appropriate, in their **original packaging**, in the storage refrigerator **immediately** on receipt. Stocks should be placed within the medicines' fridge so that those with shorter expiry dates are used first. **They must never be used when past their expiry date.**

Vaccines and refrigerated medicines must be kept within the temperature range recommended by the manufacturer (usually 2 - 8 °C). Refrigerated vaccines and medicines must **never** be frozen.

For all vaccines, a record book for deliveries, recording date and time received, batch numbers and expiry dates should be kept for each designated medicines fridge.

An example of a vaccine record form can be found in Appendix 1. It is suggested that a separate form be used for each vaccine and kept in a ring binder near the medicine's fridge.

A copy of the manufacturers' instructions is kept with the record form for reference in the event of refrigerator failure/interruption of cold chain.

7. TEMPERATURE MONITORING

The 'four Rs' of monitoring refrigerator temperatures:

- **Read:** Read temperatures at least once on every working day
- **Record:** Record temperatures on a standard form, including signing
- **Reset:** Reset after each temperature reading
- **React:** React by taking action if temperature is outside 2°C to 8°C and document this

A named / nominated individual must be responsible for monitoring the medicines fridge and ensuring backup systems are in place should the medicines fridge fail (however fridge temperature monitoring can be delegated down to other suitable trained staff members)

The following must be monitored and recorded each working day on the Fridge Temperature Checks Sheet (Appendix 2):

- The maximum temperature
- The minimum temperature
- The actual temperature
- Action taken if recorded temperature is out of range.

Following the service specific standard operating procedure for temperature checking of medicines fridges (see example - appendix 3), the temperature must be checked and recorded on a daily basis before any of the drugs are used, or for clinics which do not operate daily, at the start of each working day.

The thermometer must be reset after each reading is made and calibrated at least monthly against an independently powered external thermometer. Records must be kept by the medicines' fridge

For clinics using data logging devices – the device must be checked on every working day to ensure the alarm has not been triggered. If the alarm has been triggered, download the information and seek advice on appropriate action to take in relation to medication stability. The data logger information must routinely be downloaded and reviewed weekly.

Any medicines fridge where the temperature repeatedly falls outside the limits of 2 - 8 °C must be reported to the Estates Department for maintenance, repair or replacement. If necessary, advice on the status of the drugs can be obtained from the supplying pharmacy or the ECCH Pharmacy and Medicines Optimisation team. Also see section 10.

8. DEFROSTING AND CLEANING REFRIGERATORS

All medicines fridges must be maintained in a clean condition and should be cleaned according to manufacturer's guidelines and dated records kept.

Ice must not be allowed to build up within the refrigerator, as this reduces effectiveness. Most medicines fridges feature automatic defrosting and, in normal conditions, means that no manual defrosting is required. If the medicines fridge required manual defrosting, this must be done every 3 months and dated records kept.

When defrosting or cleaning the medicines fridge, vaccines must be transferred to a second refrigerator. This temporary storage refrigerator must also be monitored to ensure the correct temperature (2 – 8°C) is maintained. Alternatively, store the vaccines in a pre-cooled insulated container with icepacks. Continue to monitor the temperature inside the container until the usual medicines' fridge is ready for use again (refer to The Green Book for detailed information). Storage in pre-cooled insulated containers must be for a short period of time only.

9. HOME VISITS AND TRANSPORTATION

If a vaccine session is going to be carried out elsewhere, such as in patient's home, the vaccine must be transported in an appropriate size of validated medical grade cool box with a number of cool packs as per manufacturer's instruction.

The vaccine should be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage, such as being frozen.

Minimum quantities of vaccine should be transported to other sites and a record of those removed entered into the stock control book. The vaccines should be placed quickly into the validated cool boxes and opening must be kept to a minimum.

Domestic cool boxes **must not** be used to store, distribute or transport vaccines or medicines requiring refrigeration. Validated cool boxes and ice packs from a recognised medical supply company must be used and must be appropriate for the purpose required. Individual manufacturers' instructions should be strictly adhered to.

Temperatures of cool boxes must be monitored when in use, using maximum-minimum thermometers. Temperatures must be recorded at the start and end of each session.

If there are any unused vaccines, with the exception of COVID vaccines, left over at the end of a vaccination session, providing there is evidence from the temperature monitoring that the cold chain has been maintained, the vaccines can be returned to the medicine's fridge. Returned vaccines should be marked so that they can be used at the earliest opportunity.

Cold chain should be maintained for all medicinal products.

For COVID-19 vaccines, any subsequent administrations must be delivered as soon as practically possible and within 6 hours from the time of first puncture as recorded on the vial label.

10. REFRIGERATOR FAILURE OR DISRUPTION OF THE COLD CHAIN

If minimum/maximum temperature falls below +2°C or rises above +8°C the following procedure is suggested:

- Quarantine the affected stock by bagging and labelling 'Not for Use' and keep within a designated medicines fridge.
- For **non-vaccine products only**, if less than 24 hours and medicines fridge above 8°C but not more than +10°C
 - Reset min/max thermometer
 - Ensure medicines fridge door has not been left open and fridge is not overstocked
 - Check temperature again within 6 hours
 - Record the action taken and new reading on the fridge temperature record sheet.
 - If still above range, then follow the procedures below.
- Do not use any vaccine that has been out of the cold chain until advice has been sought from the manufacturer, East Anglia Medicines Information Services (tel. 01473 704431) or ECCH pharmacy team should be contacted, and the following information provided:
 - Length of time the refrigerator has been off/malfunctioning
 - Current internal temperature of the refrigerator
 - Minimum and maximum temperature during last 24 hours (temperature records should be made at least once on every working day)
 - Previous minimum and maximum temperatures
 - A list of all medicines affected date of expiry and batch numbers
- Any stock destroyed, as advised by manufacturer or pharmacist, should be replaced with new stock.
- Any salvageable products must be returned to cold chain immediately and:
 - Mark each product with date of break in cold chain and "USE FIRST" (and within the time scale suggested by manufacturer or pharmacist)
 - Mark each product with the new expiry date as advised by manufacturer or Pharmacist
- Inform the department manager who should:
 - Report on DATIX system as per ECCH Incident reporting policy
 - Complete the stock incident form on vaccine supply section of the ImmForm website if applicable
- If necessary, call out an engineer to repair the medicines fridge

Arrangements should be in place for back up facilities to be available in the event of the refrigerator failing or breaking down.

If an individual has inadvertently received a vaccine that is subsequently found to have been exposed to temperatures outside the recommended storage range, or if the vaccine is found to have passed its expiry date, advice should be sought on an individual basis from the local health protection team on 0300 303 8537. They will be able to provide or direct to the relevant expert advice.

Note: any refrigerated medicine that has not been stored at 2 – 8°C as per its licensing conditions is no longer a licensed product.

11. FURTHER USEFUL ADVICE CAN BE OBTAINED FROM THE FOLLOWING WEBSITES:

- www.dh.gov.uk/greenbook Department of Health web based version of The Green Book 'Immunisation Against Infectious Disease'
- <https://www.gov.uk/government/organisations/uk-health-security-agency> UK Health Security Agency
- <http://www.who.int> World Health Organisation (WHO). Lists vaccination schedules for individual countries
- www.medicines.org.uk/emc/ Summary of Product Characteristics (SPCs) and Patient Information Leaflets (PILs)

12. TRAINING REQUIREMENT

Any person involved in the maintenance of the cold chain must be suitably trained. Cold chain compliance must be incorporated into immunisation and vaccination training.

13. MONITORING AND AUDIT

The policy will be monitored and reviewed by the Medicines Management Group in conjunction with the Infection Prevention and Control Team. It will be fully reviewed every two years or sooner if deemed necessary due to changes in national or local guidance, professional practice or user feedback. It forms part of Controls Assurance (Safe and Secure Handling of Medicines) Audits which will be completed annually at all sites that handle medicines within East Coast Community Healthcare. The Head of Pharmacy and Medicines Optimisation will be responsible for ensuring these audits are carried out.

Cold chain compliance is incorporated into ECCH immunisation update training.

Each site will be responsible for auditing the following:

- Daily recording of min/max and actual fridge temperature
- Weekly medicines fridge contents check
- Monthly vaccine stock check
- Quarterly review of recorded temperature and stock checks

14. REFERENCES

- The Green Book Immunisation Against Infectious Disease' 2006, Department of Health (DH) Updated chapters can be found on the DH website www.dh.gov.uk/greenbook
- Royal Pharmaceutical Society of Great Britain www.rpsgb.org.uk/
- Medicines and Healthcare Product Regulatory Agency (MHRA) recommendations on the control and monitoring of storage and transportation temperatures of medicinal product
- [Vaccine cold storage, January 2010, National Patient Safety Agency](#)
- [NHS England Midlands and East Cold Chain](#)
- [Specialist Pharmacy Service \(SPS\) COVID-19 Vaccines Resources – Handling in PCN](#)
- SPS Policy for Maintaining the Vaccine Cold Chain (Primary Care)

APPENDIX 1 VACCINE DELIVERY/ REFRIGERATION RECORD

DRUG NAME:

QUANTITY	BATCH NUMBER(S)	EXPIRY DATE	DATE OF DELIVERY	TIME OF DELIVERY	TIME OF REFRIGERATION	INITIALS

APPENDIX 2 Fridge Temperature Log

Site:



Month:

Date	Time	Actual Temp	Min Temp	Max Temp	Taken by	Reset	Comments/Action taken if outside Temp range
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
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25							
26							
27							
28							
29							
30							
31							

APPENDIX 3

Suggested Standard Operating Procedures for the safe handling of refrigerated medicines

Stages of the process

Receipt of <u>refrigerated medicines</u>			
	Responsible	Risks Associated	Audit
1. Check stock against order form as soon as order arrives		Stock errors not identified. Cold chain broken.	
2. Check expiry date		Short dated/out of date stock not identified.	
3. Obtain keys to medicines fridge from authorised key-holder			
4. Place stock in medicines fridge immediately , lock medicines fridge and return keys		Cold chain broken.	

Monitoring and maintenance of medicines fridge			
	Responsible	Risks Associated	Audit
1. Medicines fridge equipped with a minimum/maximum thermometer		Unable to monitor temperature.	
2. Min & Max temperature noted and recorded at least once on every working day. Record date, time and initials		Unable to identify temperature problems. Cannot demonstrate compliance.	
3. If temperature outside 2-8°C appropriate procedure followed*		Pharmaceuticals denatured. Risk of treatment failure or adverse effect.	
4. Ensure medicines fridge NOT overstocked and NO food or drink present		Inappropriate temperature. Cross contamination	
5. Where a freezer present defrost ONCE a month		Inefficient functioning of fridge	

* Medicines fridge temperature outside 2-8°C procedure

1. Check when temperature last recorded within normal range.
2. If less than 24 hours and fridge not more than 10°C reset min/max thermometer, ensure medicines fridge door has not been left open and fridge is not overstocked, and check again within 6 hours. If still above range, then contact a member of the ECCH pharmacy team
3. If below 2°C or above 10°C, contact ECCH pharmacists
4. IN ALL INSTANCES WHERE MEDICINES FRIDGE TEMPERATURE OUTSIDE RANGE (2-8 °C) quarantine stock and do not use until you have spoken to an ECCH pharmacist.
5. Document action required by ECCH pharmacy
6. Complete DATIX incident report.