

## Tower Hamlets GP Care Group Cold Chain Policy: Storage and Transport of Refrigerated Medicines

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Date to be reviewed	Periodically or if statutory changes are required
Title	Cold Chain Policy
Supersedes	All previous Policies
This policy will impact on	All staff
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### 1.1.1 Approval Record

	Committees / Groups / Individual	Date
Consultation	Governance Committee	20 <sup>th</sup> September 2016
Approved by	Dr Joe Hall Chair, Governance Committee	31/1/2017



## **Cold Chain Policy: Storage and Transport of Refrigerated Medicines**

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## 1. Introduction

- 1.1. This policy sets the standards to ensure the cold chain is maintained and minimize the risk of compromising the safety & efficacy of refrigerated medications.
- 1.2. This policy primarily focuses on the transport and storage of vaccines but the same principles apply to any medication requiring refrigeration.
- 1.3. Failure to store medications according to manufacturers recommendations can significantly compromise the efficacy of the medication. This can cause unnecessary waste, often at considerable expense. Where vaccines are in short supply this can also impact on population health.
- 1.4. Medications not stored according to manufacturers medications can no longer be considered licensed products and manufacturers disclaim responsibility for any apparent failure of the medication.
- 1.5. Refrigerated medications must be maintained at temperatures between 2°C and 8°C up to near the time of administration. Sensitivity to changes in temperature vary dependent on the medication
- 1.6. Current practice should comply with national policy as stated in
  - 1.6.1.1. The latest version of "immunization against Infectious Disease" Chapter three 'Storage, distribution and disposal of vaccines (Public Health England)  
<https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
  - 1.6.1.2. The conditions specified in the manufacturers product licence (SPC)
  - 1.6.1.3. National Patient Safety Agency Alert "Vaccine Cold Storage" 2010  
<http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66111>

## 2. Scope

- 2.1. This policy is to be followed by all THGPCG employees, agency, locum and seconded staff working in or on behalf of THGPCG services. This policy must be used alongside the "immunization against infectious disease" (Public Health England) and Nursing & Midwifery Council "Standards for Medicines Management".  
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>  
<https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/>

## 3. Duties/responsibilities

- 3.1 Each clinical setting where vaccines or heat sensitive medications are stored must have two trained staff (designated lead and deputy) to be responsible and accountable for
  - Receipt and storage of temperature sensitive medications
  - Monitoring and recording of fridge temperatures
  - All actions in 4.3
- 3.2 The designated person and their deputy should be identified on the fridge monitoring records
- 3.3 The designated person or deputy (in their absence) is responsible for the following
  - Checking the delivery of vaccines/products for expiry, damage, leakage and evidence of correct transportation (evidence the the cold chain has been maintained)
  - Signing to acknowledge that delivery corresponds to order and safe receipt
  - Immediate storage of products in the designated storage refrigerator
  - Ensuring overstocking does not occur
  - Exercising stock rotation to prevent wastage from out of date vaccines and products
  - Removal and safe disposal of expired or damaged stock
  - Maintaining accurate and legible records of the cold chain monitoring for audit purposes

- Ensuring **Immediate action** is taken if the fridge thermometer reading is, or has been, outside the recommended range (between 2°C and 8°C) Refer to section 4.6

### 3.4 Service Leads are responsible for ensuring

- That all staff adhere to the standards in this policy
- Maintaining the cold chain as part of the organisation's business continuity plans eg refrigerator breakdown, loss of electricity supply

## 4. Procedure & Standards for Management of Refrigerated Medicines

### 4.1. Receiving Refrigerated Medicines

- 4.1.1.1. When expecting a delivery of medication requiring storage at temperatures between 2°C and 8°C the designated person or deputy must ensure that whoever accepts the delivery is aware of the need to maintain the cold chain and check the order for leakage or damage
- 4.1.1.2. All deliveries of refrigerated medicines must be unpacked immediately on arrival and placed in the pharmacy/vaccine refrigerator and not left at room temperature
- 4.1.1.3. Medications must be left in the manufacturers original packaging to protect them from light
- 4.1.1.4. Delivery notes containing batch numbers and expiry dates must be retained for 2 years from the date of receipt

### 4.2. Refrigerated Storage

- 4.2.1.1. Refrigerators used for the storage of medicines must
  - Be designed specifically for that purpose
  - Be of an appropriate size for the quantity of stock to be stored (not more than 50% full to all adequate air circulation) Order frequency should be increased rather than compromising airflow by filling the refrigerator
  - Be kept locked or in a locked room (with no public access) when not occupied by a member of staff.
  - Be reserved exclusively for the storage of vaccines and other pharmaceutical products requiring storage between 2°C and 8°C
  - Not be used to store food, drink, milk or specimens
  - Be sited in a well ventilated room maintained between 10 °c and 30°C, away from external windows and all heat sources (eg radiators and direct sunlight)
  - Be wired into a switchless fused socket to avoid being switched off accidentally, where this is not possible cover the plug and label it "Pharmacy Fridge – DO NOT SWITCH OFF"
  - Be serviced according to manufacturers instructions
  - Have it's integral thermometer independently calibrated at least annually to ensure the readings are true
  - Have an independently powered digital maximum and minimum thermometer which also records the current temperature regardless of the existence of an integral thermometer. Alternatively a data logger may be used, this should be downloaded monthly and records kept for 5 years.

### 4.1 Refrigerator Temperature Monitoring

- 4.1.1 The designated person or deputy must read and record the current, maximum and minimum temperature at the beginning of each working day. The thermometer must be reset after each recording by following the manufacturers instructions
- 4.1.2 Refrigerator temperature readings which fall outside the 2°C to 8°C range must be reported immediately to the service manager for risk assessment and action (refer to section 4.6)
- 4.1.3 The current refrigerator temperature should also be visually checked before removing any vaccine or at the start of an immunization session

- 4.1.4 Records of refrigerator temperatures must have the location of the fridge being monitored (if there is more than one fridge per room they should be individually named eg A, B, C) and should be located near the fridge. Records must be held for at least 5 years
- 4.1.5 The designated person and deputy must have training in the principles of the cold chain, how to read and reset the thermometers and know how react when the temperatures are outside of the correct range

## **4.2 Refrigerator Contents**

**4.2.1** All medicines should be stored in the manufacturer's original packaging as this is printed with the expiry date and batch number, contains a patient information leaflet and administration instructions. It also protects the product from light and damage

**4.2.2** Contents should be evenly distributed to allow air to circulate around items and shelves thus enabling the temperature to remain constant throughout the fridge.

**4.2.3** Medicines should be stored in the body of the fridge and not in the bottom drawer or door where the temperature can be higher. Storage adjacent to freezer packs should also be avoided

**4.2.4** Stock must be rotated according to expiry date and older stock placed at the front of the fridge to avoid medicines waste

**4.2.5** Expired stock must be removed as soon as possible and safely destroyed according to local policy

## **4.2 Moving vaccines between sites and for domiciliary visits/ immunization sessions**

- 4.2.1.1 Validated cool boxes and cool packs from a recognized medical supply company should be used in conjunction with validated maximum-minimum thermometers to ensure cold chain is maintained during transport. Ice packs and frozen cool packs should not be used.
- 4.2.1.2 Where there is a pharmacy fridge at the destination site the vaccine must be immediately transferred to the fridge and a record made of the maximum minimum temperature in the cool box during transport. This record must be kept for a minimum of 5 years
- 4.2.1.3 If there is no fridge available at the destination site the vaccine must be stored in the cool box until administration
- 4.2.1.4 The time between moving the vaccines from the refrigerated storage and administration should be kept to a minimum and not exceed the maximum time advised by the manufacturer of the medical cool box
- 4.2.1.5 Vaccines must be kept in the original packaging
- 4.2.1.6 Medicines that have maintained the cold chain in cool boxes should be placed in the fridge and marked "use first" along with the date it was placed in the fridge.
- 4.2.1.7 Cool boxes must be transported in the boot of the vehicle to avoid direct sunlight affecting the temperature
- 4.2.1.8 Ideally each vaccine should be taken from the cool box for each administration. However, when it is necessary to expedite a mass immunization session it may be necessary to remove a given number of doses. These doses must be kept under 25°C until administered
- 4.2.1.9 Vaccines not used within 2 hours of removal from cold storage should be disposed of in a sharps bin

## **4.3 Incidents: Fridge failure or Cold Chain Disruption**

- 4.3.1.1 Senior Managers should ensure business continuity plans are in place for storing medications in the event of refrigerator breakdown, loss of electricity or other disruptions to the cold chain. This should be implemented immediately to prevent loss of stock and disruption of immunization sessions
- 4.3.1.2 If there is any breach of the cold chain the incident must be reported via the



#### THGPCG incident reporting system

- 4.3.1.3 Vaccines that have been stored outside the specified storage requirements must not be administered without a risk assessment based on a thorough understanding of the likely impact of the temperature variation on the safety and efficacy of the medication. These medications should be quarantined within the cold chain and neither used or destroyed until advice has been obtained (refer to section 4.4)
- 4.3.1.4 If it is necessary to move stock to an alternative cold storage location stock should be marked with a black cross and the date adjacent to, or as near as possible to the batch number and expiry date. This mark denotes that it should not be used until confirmed it is safe to do so.
- 4.3.1.5 If the electricity supply has been disconnected but the temperature has remained within the 2°C to 8°C - DO NOT open the fridge door, reconnect the power and record the current temperature and maximum/minimum readings and time of the incident. Reset the thermometer.
- 4.3.1.6 If the electricity supply has been disconnected and the temperature has exceeded the 8°C limit try to establish how long the temperature has been outside of the range (either by establishing the likely time of disconnection or, if used, by downloading the data logger recordings) before seeking advice (refer to section 4.4)
- 4.3.1.7 Vaccine wastage must be reported to Public Health England

#### 4.4 Information Sources

The following sources can be consulted in the event of a potential breakage of the cold chain. The BNF also contains the contact details of manufacturers for any not listed here.

##### **Medicines Information Service (London):**

Northwick Park Tel: 020 7188 8750/020 7188 3855

##### **Individual Manufacturers Medicines Advice:**

Baxter Healthcare: Tel: 0163 520 6140

Crucell UK Ltd: Tel: 0844 8003908

GlaxoSmithKlein UK: Tel: 0800 221 4411

MASTA: Tel: 0113 238 7500

Novartis Vaccines: Tel: 08457 451 500

Pfizer: Tel: 01737 331111

Sanofi Pasteur MSD: Tel: 01628 587693

#### 5 Monitoring Compliance

Service Leads are responsible for monitoring compliance annually and reporting to the Governance and Safety Committee

#### 6 Policy Review

This policy and procedures within it will be in place for three years following approval. If changes to national guidance arise an earlier review will take place.

#### 7 Supporting References



- Department of Health. Immunisation Against Infectious Disease – The Green Book [The Green Book](#)
- Public Health England. Protocol for Ordering, Storing & Handling Vaccines [PHE Protocol for Ordering, Handling & Storing Vaccines](#)
- National Patient Safety Agency. Vaccine Cold Storage [NPSA Alert](#)



