

Policy for Maintenance of Cold Chain in Handling of Medicinal Products requiring Cold Storage

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Partners in Care

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1. Purpose

1.1 This policy aims to set out the principles by which cold chain medicines are received, stored and transported at the optimum temperature up until the point of administration to the patient.

2. Introduction

- 2.1 This document details the policy in relation to the transport, storage, safe handling and disposal of medicines requiring cold storage between 2°C to 8°C, by community staff working within Torbay and South Devon NHS Foundation Trust (TSDFT). Although this policy has been written primarily to cover the storage and transport of vaccines, the basic principles of the cold chain also apply to all medicines requiring refrigerated storage, for example insulins, eye drops, and biotech medicines.
- 2.2 This should be used in conjunction with the medicines policy and any other relevant documentation relating to medicine handling, transport, storage, administration or destruction.
- 2.3 Torbay and South Devon NHS Foundation Trust has a duty to ensure the safe care, custody, administration and destruction of medicines, for the safety of employees, those receiving services and the population at large, and to comply with current legislation pertaining to cold chain medicines and their use.
- 2.4 The cold chain system enhances the on-going quality, safety and efficacy of an immunisation programme and ensures that these standards are maintained up to the point of administration to the patient. Registered Nurses, supervisors and other health professionals who handle vaccines or cold chain medicines should do what they can to increase the use of the cold chain system, especially in satellite clinics and community hospitals and settings.

3 Protocol statement / objective

- 3.1 This protocol sets out the principles by which cold chain medicines are received, stored and transported at the optimum temperature up until the point of administration to the patient.
- 3.2 Appropriate storage facilities and monitoring of the storage conditions are available to TSDFT NHS staff to maintain cold chain.
- 3.3 It is ensured that the patient receives the appropriate prescribed medication at the optimum temperature. This is achieved by keeping accurate temperature monitoring logs of the medicine refrigerator.

4. Roles and Responsibilities

- 4.1 This policy applies to all staff, in any environment, employed by TSDFT NHS trust, working in the community services delivery unit who are authorised to receive, store, administer, transport and handle medicines requiring cold temperature between 2°C to 8°C.

- 4.2 All staff working to this policy must have knowledge of the TSDFT anaphylaxis protocol and guidelines.
https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G0337.pdf
- 4.3 All venues where immunisation is undertaken must be assessed as appropriate for the purpose of which it is to be used (e.g. facilities, lighting, seating, ventilation, hand washing, ability for private consultation).
- 4.4 Service / ward / unit managers are responsible for ensuring their staff follows the guidance in this policy.

5. General Principles

- 5.1 All medicines requiring cold storage or refrigeration must be stored according to the manufacturer's instructions between 2-8° Celsius. These include vaccines, insulin and any other medicinal products classified as high risk, because they are at risk from freezing as well as from elevated temperatures.
- 5.2 All vaccines must be refrigerated and protected from light. They must not be frozen. The efficacy of the vaccine depends upon their temperature being kept within the range 2-8° Celsius between dispatch from the manufacturer and receipt by the patient. Temperatures above this range can reduce the vaccine's potency leading to failure to produce satisfactory levels of immunity. The effect is cumulative and may be considered to start at the point where the manufacturer delivers the product, ending when given to the patient.
- 5.3 Temperature below 2°C or freezing can cause deterioration of the vaccine which can lead to failure to produce satisfactory levels of immunity and also lead to hairline cracks in the ampoule, vial or pre-filled syringe, which could potentially allow the contents to become contaminated.
- 5.4 Everyone who is involved in vaccination receipt, storage and handling must be trained in the need to maintain the cold chain.
- 5.5 Each site where vaccines are used will require a named person who is responsible for ordering, receipt and safe storage of vaccines. There should be a designated person to cover in times of absence.

6. Receiving Cold Chain Medicines and Vaccines

- 6.1 Cold chain medicines and vaccines delivered directly to Torbay hospital pharmacy or community hospitals by wholesalers should maintain cold chain during the transport.

- 6.2 A named and trained person(s) at Torbay hospital pharmacy and at each community hospital and department should be responsible for the storage of refrigerated medicines and vaccines on arrival.
- 6.3 The courier or driver must give the container to an authorised person who will sign for the delivery and record the time of receipt on the delivery notice.
- 6.4 Medicines in a vaccine carrier or validated cool box from distributors should be clearly labelled as “Refrigerated Medicines and Store in Refrigerator on receipt”
- 6.5 On receipt of the delivery the designated person should check for damage and maintenance of cold chain. Torbay hospital pharmacy or supplier needs to be contacted straight away if there is a problem.

7. Appropriate Storage Facilities for Cold Chain Medicines and Vaccines

- 7.1 Standard domestic refrigerators are not suitable for storing cold chain medicines or vaccines. This is because they have uneven temperature distribution due to minimal air circulation and a normal operating range of between 0^oC and 10^oC . There is also risk the cold chain medicines or vaccines could freeze if they come into contact with the chiller plate or coil at the back of the fridge.
- 7.2 Purpose–built pharmacy refrigerators should be used for the storage of all cold chain medicines and vaccines. This is because these pharmacy refrigerators provides a uniform temperature control by circulating the air within them and a rapid fall in temperature after the refrigerator door has been opened.

8. Record Keeping

8.1 The medicine refrigerator must have its own record system or stock control monitoring form for vaccines and should state the followings;

8.1.1 Specifically upon receiving vaccines the designated / named person must record:

- The name of the vaccine
- The quantity received
- The date and time they were put in the fridge
- The name and signature of the designated person receiving the vaccine
- The batch number, expiry date, manufacturer and supplier

8.1.2 Staff removing vaccines from the fridge must record:

- The name and batch number of the vaccine removed
- The quantity removed
- The date and time removed
- The name and signature of the clinician

8.2 The designated / named person is responsible for maintaining and monitoring the fridge temperature on each working day, using an approved minimum / maximum thermometer. Each medicine refrigerator must have a designated record system specifically for this purpose, in which must be recorded:

- The actual fridge temperature must be between 2-8° celsius
- The date and time of monitoring
- The minimum and maximum temperatures since the last reset
- Confirmation of the thermometer reset
- The name and signature of the designated person performing the monitoring and stating any occurrences e.g. known reasons for temperature fluctuations, any stock requiring quarantine.

All fridge temperature measurements should be documented on the relevant “Medicine Refrigerator Temperature Monitoring Form” (see Appendix 2)

8.3 The names and contact numbers of appropriate people to contact in times of concern should also be kept in the front of the fridge temperature monitoring book or recording system. These can be a line manager, estates, medicines optimisation pharmacy team at Torbay hospital depending on the situation. These contacts should be consulted whenever the stability of the vaccine or refrigerated medicine is in any way compromised, such as possible fridge failure.

8.4 In regard to repair and maintenance, TSDFT medical devices policy states that: ‘Community based equipment and individually held equipment are subject to annual rotation to support cleansing, calibration and maintenance. (Appendix VII Infection Control policy and Appendix IV Decontamination policy)’.

9. Storage

- 9.1 Pharmaceutical grade fridges must be used in all community hospitals, health care centres and care home residential units.
- 9.2 The fridge must be registered with Medical Electronics and serviced and calibrated as per service schedule.
- 9.3 Vaccines and medicines requiring cold storage must be stored in the medicine refrigerator immediately upon receipt and must not be left at room temperature.
- 9.4 The refrigerator must not be overfilled (no more than 50% of internal space). There must be space for air to circulate, and to maintain constant temperature.
- 9.5 Vaccines and medicines requiring cold storage should not be stored in the fridge door nor on the bottom of the fridge to ensure air circulation and consistent temperatures throughout. Stock must be rotated and expiry dates checked regularly (once a week) by a named / designated member of staff.
- 9.6 Steps must be taken to ensure that the fridge is not switched off accidentally, for example by clearly labelling the fridge plug (Do NOT Switch off) or using a switchless socket.
- 8.7 An approved maximum / minimum thermometer should be used with the monitoring probe sited in a central location within the refrigerator, preferably within the products, and with the display outside the unit.
- 9.8 A digital thermometer may be necessary if large bulks of stock are being received and stored. A risk assessment must be carried out and advice sought from the Head of Provider Pharmaceutical Services.
- 9.9 Consideration should be given to the fitting of a 24 hour alarm system where the refrigerator regularly stores large quantity of vaccines or medicines requiring cold storage.
- 9.10 The refrigerator seal must be inspected daily and replaced immediately if damaged or not intact.
- 9.11 There should be agreed alternative storage arrangements for use in the event of a power failure or fridge breakdown. Alternative arrangements are also required whilst the fridge is being defrosted.
- 9.12 The refrigerator must not be used to store anything other than medicines and/or transportation cool packs. It must not be used to store specimens, blood products, food or drink.
- 9.13 The refrigerator must be locked at all times and the access to refrigerated medicines restricted as for other medicines

9.14 Vials, ampoules or pre-filled syringes must not be taken from their packaging during storage; this could lead to damage of vaccines by exposure to light. In addition to possible loss of information on batch number, expiry date etc.

10. Packaging and Transport from Torbay Hospital Pharmacy to Satellite Clinics

10.1 The health professional who is carrying out the vaccinations at the satellite clinic is solely responsible for ensuring the correct transportation of vaccines and maintenance of the cold chain during this process.

10.2 Only the minimum quantity of vaccine should be taken to clinics at other sites.

10.3 Validated rigid type cool boxes (with minimum and maximum thermometer) should be used for transportation of vaccines to other sites. Validation records of all equipment should be kept and maintained by the manager of the service providing the vaccination service.

10.4 Validated cool boxes and packaging material should be stored at the lowest possible temperature prior to packing with the vaccine load.

10.5 Vaccines should be packed in the validated cool box as late as possible and packed / transported according to the cool box and vaccine manufacturers' instructions.

10.6 Refrigerated cool packs should be used wherever possible. They must be insulated to prevent direct contact with the vaccine. Vaccines should be insulated to prevent direct contact between cool packs and vaccines, i.e. by using polystyrene chips (refer to cool box instructions).

10.7 Cool packs should be arranged so that one is at the bottom of the cool box and another is at the top.

10.8 Space left within the cool box after packing vaccines must be loosely filled to minimise circulating air i.e. by using polystyrene chips.

10.9 On arrival at the vaccination session, vaccinations should be transferred to a refrigerator if available. Otherwise they must be left in the closed box until needed.

10.10 Any unused vaccine which has been involved in transportation may be placed back into stock provided they are intact, within their original packaging and the registered professional can guarantee that the cold chain has not been broken by validating using the thermometer probe to check the internal temperature of the transportation cool box. If in any doubt destroy the vaccine (see section 9) unless there is documented evidence specific to an individual vaccine to prove efficacy. All vaccine returned to stock **MUST** be clearly marked 'USE FIRST' by the registered professional with the date of transport to ensure that they are used first when transported to a clinic for a second time. Return of vaccine to the stock fridge for a second time must not occur.

11. Disruption of the Cold Chain

11.1 In the event of cold chain failure, do not use any vaccine or medicines, contact Torbay hospital pharmacy, Medicines Information department and Medicine Optimisation department. Document all advice received. The following information is likely to be required:

- How long the medicine has been out of the cold chain
- The temperature that the vaccine has reached (i.e. room temperature), or the actual, minimum and maximum temperature readings recorded on the fridge thermometer
- When the correct temperatures were last recorded
- If dealing with vaccines, the names, batch numbers and expiry date of the vaccines
- When seeking advice, highlight any product already labelled as 'USE FIRST'.

11.2 Disruption to the cold chain should also be reported on the incident reporting system.

11.3 Arrange for vaccines and medicines requiring cold storage to be returned to correct storage conditions immediately. Ensure safe quarantine of the affected products until their efficacy can be guaranteed. Place the affected vaccine separately and label clearly "Do NOT Use & for Quarantine".

11.4 If advised that the medicine may still be used, ensure that these medicines are used first. This may be done by marking the outer packaging.

11.5 UKMI (United Kingdom Medicine Information) have produced a website to assist healthcare professionals to determine the continued efficacy of medicines requiring cold storage when the cold chain is broken. The web address is <http://www.ukmi.nhs.uk/applications/fridge/>. The user name is **artic** and the password is **f7idge**. Enter the name of the medicine in the text box and press search or follow the website for further guidance. Please note this website is not exhaustive.

11.6 All vaccines and many other medicines which are stored at temperatures at 0° celsius or below will require disposal. Freezing vaccines causes deterioration and can give rise to increased adverse reactions by:

- Irreversibly denaturing the proteins in the vaccine
- Reducing the efficacy of the vaccine
- Causing the emulsions in the vaccines to become unstable
- Producing hairline cracks in the ampoule/vial/prefilled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

12. Disposal

12.1 All medicines must be disposed of in accordance with the Trust's Waste Management Policy.

- 12.2 Any prepared or opened vaccine or medicine requiring cold storage must be disposed of at the end of the session, or sooner if the manufacturers recommended period has expired.
- 12.3 In the case of any unused or partially used vaccine (prefilled syringes, ampoules, vials), they should be disposed of at the end of an immunisation session by sealing in a proper, puncture-resistant 'sharps' box (UN-approved, BS 7320).
- 12.4 Any contaminated waste and expired vaccines must be disposed of in the appropriate sharps bin (UN-approved, BS 7320).
- 12.5 Sharps bins should be returned to the base clinic after each session unless they can be stored in a suitable locked cupboard with a key held by approved personnel and should not be accessible to any unauthorised individual. The 'sharps' container should be replaced once it is two-thirds full.

13. Spillage

- 13.1 Every clinic / ward must have a copy of the COSHH safety data sheets of the products used and a spillage kit.
- 13.2 If spillage of a medicine or vaccine occurs, it must be cleared quickly; gloves and a disposable apron should be worn. The spillage should be soaked up with paper towels immediately, taking care to avoid skin puncture from glass or needle.
- 13.3 The area should be cleaned with a chlorine-releasing product, according to the local chemical disinfection policy or COSHH safety data sheets.
- 13.4 Spillage on skin should be washed with soap and water. Report to Occupational Health for further medical advice and complete an incident form.
- 13.5 If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought. Report to Occupational Health for further medical advice, complete an incident form.

14. Training

- 14.1 It is the responsibility of the service manager to ensure that all staff have knowledge of this policy and are competent in maintaining the cold chain for medicines requiring cold storage and monitoring daily temperature of medicine refrigerator.

15. Audit

- 15.1 An annual audit will be undertaken of all sites where cold storage is required. This audit will be in the form of an unannounced visit using the tool in appendix 2.
- 15.2 This audit will form part of the annual audit plan for each year.

- 15.3 A report of finding and where applicable a timed action plan to be completed by the service area.
- 15.4 In addition, cold storage will be assessed as part of safe and secure audits conducted by the medicines optimisation team.

16. References

- Nursing matters factsheet – The vaccine cold chain: maintaining cool links – International Council of Nurses: www.icn.ch/matters (2009)
- Immunisation against Infectious disease the Green book www.dh.gov.uk/greenbook 09/2014
- Medicines Policy for Registered Professional - Standards for the Supply, Storage and Administration of Medicines (June 2015)
- Trust waste Management Policy
- Protocol for ordering , storing and handling vaccines
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf

Appendix 1: REFRIGERATOR TEMPERATURE MONITORING

The temperature of the medicines refrigerator should be monitored and recorded daily by a named designated person, using a maximum/minimum thermometer. The temperature should be checked daily on each working day.

Member of staff responsible for taking temperature readings:

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Deputies who will complete this task when the above is absent:

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Most pharmaceutical products that require refrigeration should be stored within the range 2 – 8 °C, but always check the pack to confirm.

In order to spot any problems that have occurred overnight, the temperature should be checked daily (preferably at the same time each day).

Record the date, time, and maximum / minimum thermometer readings on the Temperature Record Sheet and sign the form. Reset the thermometer after taking the reading.

Keep the Record Sheet on or near the refrigerator.

Most medicines refrigerators are fitted with integral digital maximum / minimum thermometers. Please follow the instructions for taking temperature readings and resetting on the front of the refrigerator.

When this is not the case, a British Standard maximum / minimum thermometer should be used. The thermometer should be left in the refrigerator at all times, except when being read, unless the thermometer is external to the refrigerator. The actual / present temperature should be read as quickly as possible on opening the refrigerator door. After taking a reading and resetting it should be replaced in the correct position (as advised by the manufacturer), ensuring that the door is securely closed and locked.

In the event of temperature readings outside of the range 2 – 8 °C or refrigerator failure, then advice from the Torbay Hospital Trust Medicines Information Department should be sought.

Checked by Medicines Optimisation Pharmacy

Month

Year.....

Appendix 3

TSDFT PHARMACY SERVICES

AUDIT OF MEDICINE REFRIGERATORS ON WARDS / UNITS

NAME OF AUDITOR:

DESIGNATION OF AUDITOR:

Department / Unit

Date

Is the refrigerator used to store medicines on the units a domestic appliance or an approved pharmaceutical / medicines refrigerator?

Serial number & make of appliance:

Is the refrigerator in good condition and regularly serviced?

Is the refrigerator locked? YES / NO (please delete)

Who has custody of the keys? (Name and Job Role)

Does the refrigerator have a suitable maximum and minimum thermometer?

YES / NO (please delete)

Is there a daily record kept of the refrigerator's temperature? (This includes actual, maximum and minimum temperatures)

Where are records kept / archived?

Who is the designated person who monitors the temperature of the fridge? (Name and Job Role)

At the time of the audit, what was the temperature?

Is the refrigerator defrosted (if not automatic) and cleaned regularly?

Is a record kept of this?

What happens to the medicines when the fridge is being cleaned and defrosted?

Is the fridge wired directly into the electrical socket or the plug taped over to prevent the accidental switching off of the appliance?

Is the fridge large enough to accommodate the medicines stored within, while ensuring that it is not more than 50 % full?

Is stock rotation of medicines being carried out?

Are there any foods or drink items, or specimens such as urine or blood being stored in the fridge with the medicines?

Does your unit transfer any refrigerated stock to an alternative location either for storage or administration? If yes, provide details of cold bags / transportation organisation / validation and proof of equipment

Do you vaccinate children? If so you must keep and have evidence of all records of administration, expiry date, batch number etc until the patient's 25th birthday or 8 years after the death of the child. Do you comply?

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Appendix 4

TSDFT SPECIFICATION FOR MEDICINES' REFRIGERATORS

The medicines refrigerator should meet the following criteria:

TEMPERATURE RANGE

The General Pharmaceutical Society specifies the temperature range of between 2 – 8°C.

THERMOMETERS

All medicine refrigerators must have a maximum/minimum thermometer, regardless of the existence of an integral thermometer.

All medicine refrigerators should ideally have two thermometers, one of which is a max/min thermometer independent of mains power. If only one thermometer is used, then a monthly check should be considered to confirm that the calibration is accurate.

Temperatures should be monitored and recorded daily by a named designated person – see Appendix 1

TEMPERATURE DISTRIBUTION

The refrigerator should maintain the temperature range across its entire load area

In order to conform with this specification the refrigerator should –

NOT CONTAIN A FREEZER COMPARTMENT. Items placed against or close to the freezer compartment will also freeze which will destroy most medicines

NOT CONTAIN ANY INSULATED TRAYS as these insulate the product and cause temperature to rise

MAY CONTAIN A FAN TO CIRCULATE THE COLD AIR

CAPACITY

The medicines refrigerator must not be overfilled. Adequate air must be allowed to circulate inside the refrigerator for temperature stability. Medicines should also not be stored within the compartments in the refrigerator door

ELECTRICAL SUPPLY

The medicines refrigerator should be wired directly in the electrical socket or appropriate steps taken (such as taping over the plug) to ensure that the refrigerator is not accidentally switched off. Power alarms may be purchased which sound if power to the refrigerator is switched off.

In such an event expert advice on the medicines contained should be sought

SECURITY

The medicines refrigerator should be lockable and should be stored in an area not easily accessed by the public

When not in use, the refrigerator MUST be kept locked at all times, and the keys retained by an authorised person

MEDICINES ONLY

The medicines refrigerator should be reserved SOLELY for the storage of pharmaceuticals.

Food or drink items or specimens such as blood or urine must NOT be stored in the medicines refrigerator

CLEANING & SERVICING

The medicines refrigerator should be serviced, defrosted (if not automatic) and be cleaned on a regular basis

An alternative refrigerator or validated cool bags should be available to store the refrigerators' contents during the process