Cold Chain Policy for Medicines and Vaccines

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Partners in Care

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Document Information

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Links or overlaps with other strategies/policies:			
All TSDFT Trust Strategies, policies and procedure documents			

Amendment History

Issue	Status	Date	Reason for Change	Authorised
0.1	Draft	September 2015	Review and Amalgamation of two Cold Chain Policies	Pharmacist
V 1.0	Ratified	December 2015	Amalgamation of two Cold Chain Policies	Care and Clinical Policies Group
1	Ratified	13 October 2017	Review date extended	Care and Clinical Policies Group
1	Ratified	09 March 2018	Review Date Extended	Care and Clinical Policies Group
2	Ratified	27 July 2018	Revised	Care and Clinical Policies Group Medicines Management Committee

Contents

1. Purpose

1.1 This policy sets out the process, procedures and equipment required to ensure that medicines requiring cold storage are managed appropriately. This includes transport, storage, safe handling and disposal. The basic principles of the cold chain apply to all medicines requiring refrigerated storage**,** for example insulins, eye drops, and vaccines.

2. Introduction

2.1 In order to ensure safety, efficacy and the manufacturer's expiry date, the temperature range of certain medicines need to be maintained between 2-8˚C during every stage of the medicines trail (e.g. storage, transport, packaging). This is often referred to as "maintaining the cold chain." If the cold chain is broken (i.e. if the medicines become too hot or too cold at any time), such medicines may lose their effectiveness quickly or become potentially dangerous. Some cold chain items, such as vaccines, insulin and biotech products, can be classified as high risk because they are at risk from freezing as well as from elevated temperatures. Other products may be labelled as requiring storage between 2-8˚C, and a short deviation from this temperature range presents less of a danger to users. However, no distinction is made in practical terms in respect of storage requirements and controls, and this procedure applies to all products requiring storage at temperatures below ambient. Deviation from the cold chain is not only a patient safety risk but costs the NHS money.

2.2 In addition to requiring a cold chain, many of these medicines are also Prescription Only Medicines (POM) and therefore need to be stored securely.

2.3 National Patient Safety Agency (NPSA) Rapid Response Report 008 has identified a number of incidents related to vaccine cold storage. Themes identified from these reports include: delay in storage of vaccines (especially after delivery); storage at wrong temperature; fridge switched off (in error) or broken; power cut or fridge door left open; no temperature monitoring; inadequate or missing equipment; and inappropriate use of domestic fridges.

2.4 This should be read in conjunction with the medicines policy and any other relevant documentation relating to medicine handling, transport, storage, administration or destruction.

2.5 Medicines that have not been stored as specified within their manufacturer's summary of product characteristics are no longer within the terms of their product licence and any use of them is the responsibility of the user.

3 Objective

3.1 To set out clearly the process 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 To ensure staff are aware of their roles and responsibilities in maintaining the cold chain.

3.3 To ensure that cold chain medicines are safe and effective when administered to patients.

4. Roles and Responsibilities

4.1 This policy applies to all staff employed by TSDFT who are authorised to receive, store, administer, transport and handle medicines requiring storage between 2-8˚C.

4.2 TSDFT has a duty to ensure the safe storage, transport, handling, and administration and disposal of cold chain medicines and to comply with current legislation.

4.3 Registered Nurses and other staff who handle cold chain medicines or vaccines must ensure that the cold chain is maintained at all times.

4.4 Managers are responsible for ensuring that their staff follows the guidance in this policy.

5. General Principles

5.1 All medicines requiring cold storage must be stored according to the manufacturer's instructions between 2-8˚C as they are at risk from freezing as well as from elevated temperatures. These medicines include vaccines and insulin.

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˚C between dispatch from the manufacturer and receipt by the patient. Temperatures above or below 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 Temperatures below 2˚C or freezing can lead to hairline cracks in the ampoule, vial or pre-filled syringe in which the medicines are supplied; this can potentially allow the contents to become contaminated.

5.4 Each site where vaccines are used will require at least 2 named people (ideally 1 from the nursing team and 1 from management) who are 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 that are delivered directly to Torbay hospital pharmacy or community hospitals by wholesalers must have their cold chain maintained during the transport.

6.2 The courier or driver must give the cold storage container (clearly labelled as "Refrigerated Medicines and Store in Refrigerator on receipt") to an authorised person who will sign for the delivery and record the time of receipt on the delivery notice.

6.3 A named and trained person(s) at Torbay hospital pharmacy and at each ward, department or community hospital should be responsible for the immediate storage of refrigerated medicines and vaccines on arrival.

6.4 On receipt of the delivery the designated person should check for any discrepancy, leakage or damage and maintenance of the cold chain. Torbay hospital pharmacy or the supplier needs to be contacted straight away if there has been any disruption to the cold chain.

7. Fridge Specifications

7.1 **TYPE:** Purpose designed pharmacy refrigerators must be used for the storage of all cold chain medicines and vaccines. These specialised refrigerators provide a uniform temperature by circulating the air within them and a rapid fall in temperature after the refrigerator door has been opened. They are also Department of Health 'Immunisation against infectious Disease (Green Book) compliant. Approved fridges are available through Agresso.

7.2 **ELECTRICAL SUPPLY:** Refrigerators must be hardwired into a fused spur to ensure that they are not accidentally switched off. If this is not possible the fridge plug must be labelled 'Fridge Do NOT Switch Off'. If a medicines refrigerator is turned off for any reason it must be switched on and the temperature monitored and recorded at least twice daily for 48 hours before any medicines or vaccines are stored in it. There should be an agreed alternative storage arrangement for use in the event of a power failure or fridge breakdown. Alternative arrangements are also required whilst the fridge is being defrosted.

7.3 **MAINTENANCE:** Refrigerators must be registered with Medical Electronics and serviced and calibrated as per their service schedule. Vaccine refrigerators must be serviced and temperature calibrated yearly. They must not be situated near a radiator or any other heat source and good ventilation must be maintained to ensure good working conditions. The refrigerator seal must be inspected daily and replaced immediately if damaged or not intact. Fridges should be maintained in a clean condition and ice should not be allowed to build up.

7.4 **CAPACITY:** The refrigerator must not be overfilled (no more than 50% of internal space). There must be space for air to circulate, and to maintain a constant temperature. Opening of the fridge door should be kept to a minimum.

7.5 **TEMPERATURE DISTRIBUTION:** Vaccines and medicines requiring cold storage should not be stored in the fridge door nor on the bottom of the fridge this ensures good air circulation and consistent temperatures throughout.

7.6 **THERMOMETER:** 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. This is obtained from the pharmacy department. 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.

7.7 **SECURITY:** The refrigerator must be locked at all times and the access to refrigerated medicines restricted as for other medicines unless a Medicines Security Risk Assessment has been complete (hospital sites only).

8. Storage

8.1 Vaccines and medicines requiring cold storage must be stored in the medicine refrigerator immediately upon receipt and must not be left at room temperature.

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

8.3 Stock must be rotated and expiry dates checked regularly. Frequency of checks will depend on the area and stock turnover.

8.4 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. Record Keeping

9.1 The medicines refrigerator must have its own record system or stock control monitoring form for **vaccines** and should state the following;

9.1.1 Specifically upon receiving vaccines the designated 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

9.1.2 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

9.2 The designated persons are responsible for maintaining and monitoring the fridge temperature on each working day, using an approved minimum / maximum thermometer and recorded in the fridge temperature monitoring booklet (available from pharmacy). The following must be recorded:

- The date and time of monitoring
- The current fridge temperature (must be between 2-8˚C)
- 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 actions taken due to any occurrences e.g. known reasons for temperature fluctuations, any stock requiring quarantine.

9.3 In regard to repair and maintenance, TSDFT medical devices policy states that: 'Community based equipment and individually held equipment is subject to annual rotation to support cleansing, calibration and maintenance.'

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

10.1 The registered nurse who is carrying out the vaccinations at the satellite clinic is 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 medical grade rigid type cool boxes and cool packs (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. 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.

10.5 Refrigerated cool packs should be used wherever possible. They must be insulated to prevent direct contact with the vaccine. Vaccines must be loosely packed and be insulated to prevent direct contact between cool packs and vaccines, i.e. by using polystyrene chips (refer to cool box instructions). Cool packs should be arranged so that one is at the bottom of the cool box and another is at the top.

10.6 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 minimising the exposure of the vaccines to room temperature.

10.7 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 12) 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 medicine, keep the refrigerator door closed and contact Medicines Information at Torbay hospital pharmacy on 01803 655304 (55304 internally) or out of hours the on call pharmacist via switchboard. 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 items 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 with the reduced expiry date.

11.5 All vaccines and many other medicines which are stored at temperatures at 0˚C 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 requiring cold storage must be disposed of at the end of the session, or sooner if the manufacturers recommended period has expired. Other medicines should be disposed of if they have reached their expiry or are for single use only.

12.3 In the case of any unused, partially used, expired vaccines, contaminated waste or medicines in prefilled syringes, ampoules or vials, they should be disposed of by placing in a proper, puncture-resistant 'sharps' box (UN-approved, BS 7320). This must be

sealed at the end of the immunisation session or where appropriate when the container is full.

12.4 In the community sharps bins should be returned to the base clinic after each session unless they can be stored in a suitable locked cupboard only accessible to an authorised 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 (supplied with the product or available from the manufacturer) for vaccines 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 broken glass or needles. Contaminated gloves, towels etc. must be sent for incineration.

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 on the Trust incident reporting system.

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 on the Trust incident reporting system.

14. Training

14.1 It is the responsibility of the service/ward/department 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 Managers must review the temperature monitoring logs to ensure that discrepancies are reported and acted upon.

15.2 In addition, cold storage will be assessed as part of the Safe and Secure six monthly audits conducted by the pharmacy team.

15.3 For vaccine fridges:
Every week – fridge contents should be checked at least once
Every month – vaccine stock should be audited and recorded

Every three months – share audit records of stock and temperature management with your local screening & immunisation teams

16. References

- Immunisation against Infectious disease the Green book https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Medicines Policy for Registered Professionals in Community Services Delivery Unit https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G1927.pdf
- Medicines policy for wards and departments at Torbay hospital https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G0806.pdf
- Trust waste Management Policy https://icon.torbayandsouthdevon.nhs.uk/areas/waste/Pages/procedures.aspx
- 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

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS South Devon and Torbay Clinical Commissioning Group Torbay and South Devon NHS NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		**Version and Date**	
Policy Author			

An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

Who may be affected by this document?

Patients/ Service Users ☐	Staff ☐	Other, please state… ☐

Could the policy treat people from protected groups less favorably than the general population?
PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below

Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐

Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)	Yes ☐ No☐

Please provide details for each protected group where you have indicated 'Yes'.

VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language[5] used throughout?	Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?	Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☐

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way?	Yes ☐ No☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

Who was consulted when drafting this policy?

Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐
Staff ☐	General Public ☐	Other, please state… ☐

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☐

ACTION PLAN: Please list all actions identified to address any impacts

Action	Person responsible	Completion date

AUTHORISATION:
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

Name of person completing the form		**Signature**	
Validated by (line manager)		**Signature**	

Please contact the Equalities team for guidance:
For South Devon & Torbay CCG, please call 01803 652476 or email marisa.cockfield@nhs.net

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation.

[1] Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, NDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.