

Medicines Policy Part 3: Cold Chain standards

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Author		Medicines Management
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1	June 2012	V1 Shropshire Community Health NHS Trust (SCHT)
2	September 2014	V2 to incorporate green book updates and new services.
3	June 2017	V3 updated central vaccine ordering info and fridge monitoring sheet. Records retention clarified. New monitoring form added and SOP removed.
4	July 2020	Scheduled review. Additional clarity given to tasks. Updated link to Immform and combine fridge and ambient temperature recordings to one form. Audit process strengthened to include additional services. Audit form amended to combine fridge and ambient temperature checks.

Medicines Policy

Part 3: Cold Chain Standards for Vaccines and Pharmaceuticals

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1. Introduction

Rationale for development

The efficacy and safety of pharmaceuticals, including vaccines, requiring controlled low temperature storage ultimately depends on the maintenance of temperatures within the manufacturers' recommended range, typically 2-8°C. If the storage recommendations are not followed, manufacturers can disclaim responsibility for any apparent failure of the product.

These standards have been developed to ensure that manufacturers' recommendations are adhered to, in order to protect individual patient care.

This policy will not discuss the storage, use or disposal of parenteral nutrition or chemotherapy. Services that use chemotherapy must ensure they have local SOP's in place to protect staff as per the Health and Safety at Work Act 1974.

2. Aims

To provide standards to anyone handling vaccines within Shropshire Community Health NHS Trust (SCHT) for maintaining the cold chain and thereby reducing the risk of compromising the quality and safety of the products administered to their patients.

3. Definition

The cold chain can be defined as the storage and transport of pharmaceuticals requiring controlled low temperature storage between 2-8°C from manufacturer until the point of administration to a patient.

Fridge line pharmaceutical is defined in this document as any medicine requiring storage between 2-8°C.

4. Background

Inadequate temperature control during storage and transport of vaccines or fridge line pharmaceuticals can reduce the efficacy of the product.

Vaccines are biological substances that may lose their effectiveness rapidly if they become too hot or too cold at any time. This is particularly important during transport and storage of the vaccine and failure to provide the correct storage conditions can result in compromised attainment of a satisfactory level of immunity.

Freezing can irreversibly denature proteins and products such as emulsions may become physically unstable. It can cause deterioration of and increased reaction to vaccines. Freezing can also produce hairline cracks in the ampoule/vial/pre-filled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

Heat can cause loss of potency and reduces the shelf-life of the vaccine so its effectiveness cannot be guaranteed if stored outside of the recommended temperature.

Prolonged exposure to light (particularly ultra violet) will also cause loss of potency.

5. Authority to order

At least two individuals must be nominated / named to be responsible for the ordering, receipt and care of vaccines within each clinic so that there is always an authorised person able to place an order on site.

Staff with responsibility to order vaccines must ensure they have the necessary legal requirements in place for the subsequent possession of vaccines.

6. Ordering

Vaccination stocks must be monitored regularly by the nominated individuals.

Services will order vaccines on a regular basis to maintain appropriate stock levels in order to avoid over/under stocking and vaccines expiring before use. Services must hold no more than 2-4 weeks supply of vaccine at any time.

Services will place their orders using the forms provided by the supplier of the vaccine, and order in sufficient time so that there is always adequate supply for the clinics.

Failure to ensure correct stocks of vaccines and inadequate stock rotation procedures across all areas that store vaccines, whether for a clinic or individual use, will increase the cost to the NHS.

For those vaccines purchased centrally register for an ImmForm account at <https://portal.immform.phe.gov.uk/>

7. Receipt of vaccines from supplier

All orders must be checked on receipt for leakage, damage and discrepancies before accepting and signing for the delivery. In the event of a discrepancy, do not sign for the order but contact the supplier and follow their instructions.

The vaccines must be refrigerated immediately, removing all excess packaging but leaving the vaccine within the original manufacturers' packaging. They must not be left at room temperature.

It is the responsibility of the named individuals at each site to ensure that all documentation in relation to vaccine orders and receipts is accurate and up to date.

The vaccine type, brand, quantity, batch numbers and expiry dates must be checked against the delivery sheet. The date and time at which the delivery was received written on the delivery sheet along with a signature of who checked them off.

The delivery note must be retained on site for 2 years.

8. Ordering and receipt of fridge-line pharmaceuticals in all Shropshire Community Health NHS Trust settings

Fridge-line pharmaceuticals can be ordered in the same way as other pharmaceutical products.

All orders must be checked and signed for on receipt of the delivery. In the event of a problem do not accept the order and contact the supplier.

Immediately after checking, the product must be unpacked from the transport container, left in its original manufacturing packaging and placed into the fridge, **remembering to rotate the stock so that products with the shortest expiry date are used first**, by placing the shortest expiry at the front of the fridge.

The delivery note / invoice must be signed by whoever checked off the fridge-line and retained for a minimum of 2 years. See section 7.

9. Storage conditions

As well as maintaining the fridge temperature, the named individuals must also ensure the following:

The fridge must be a specialised refrigerator for storage of pharmaceuticals or vaccines between +2°C and +8°C (aim for midpoint +5°C). Ordinary domestic fridges must not be used. The Medicines Management Team or the Estates Department (MPFT) can be contacted for advice on fridges suitable for drugs.

The fridge must be uniquely identified by its serial number.

The fridge must be dedicated to storing pharmaceutical products only. Clinical specimens must be stored in another fridge.

As a number of the medicines stored under cold chain are 'Prescription-Only-Medicines' (POM), all fridges **must** be kept locked or be in a locked room, which is inaccessible to unauthorised staff or the public.

The fridge must not be sited in front of a radiator.

Ensure that the fridge is of the correct size so that there is enough space for air to circulate freely around the back of the fridge, particularly during seasonal vaccination programmes where stock levels are higher than normal i.e. flu vaccination programme.

The fridge plug must be secured to avoid disconnection (i.e. Wired directly into a switchless socket) or labelled "Do not switch off".

Regular visual inspections, portable appliance testing (PAT) and adherence to the electricity at work regulations 1989 must be done to ensure the fridge is safe and fit for purpose.

The fridge must be monitored with a digital minimum / maximum thermometer, which also records the actual current temperature.

For external thermometers, the naked probe should be suitably housed to simulate packaged pharmaceuticals and to minimise fluctuations in temperature caused by air movements. This can be achieved by placing the probe in a bottle, according to manufacturer's instructions. The bottle is then placed inside the refrigerator to mimic storage in vials. For further guidance, contact the Estates Department.

A maintenance contract must be in place to ensure yearly servicing of the fridge and calibration of the thermometer. If only one min / max thermometer is in use then this should be checked monthly to ensure the calibration is still accurate. All servicing and calibration checks must be documented and kept by the fridge.

The fridge must be regularly cleaned and defrosted according to the manufacturer's instructions and records kept by the fridge.

There is a need to prevent build up of ice, as this can have a impact on the maintenance of temperatures within the fridge. 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 a validated cool box.

The contents should be evenly distributed within the fridge to allow air to circulate. Products must not be placed in the door or bottom drawers. The fridge must not be overfilled (not more than 50% is the recommendation of the Health Protection Agency)

Out of date stock must not be stored in the fridge – see section 12

Any unused vaccines that have been exposed to temperatures below +2°C or above +8°C must be returned to their correct storage conditions, segregated from other stock and labelled 'do not use' until further advice gained. Contact the manufacturer or Shropshire Community Health NHS Trust Medicines Management Team for stability information and follow their guidance.

Reconstituted Vaccines

Some vaccines need reconstituting with a diluent. In these cases, best practice must always be followed, e.g. reconstitution occurs immediately before use and never in advance.

Any reconstituted vaccine that isn't administered straight away must be disposed of, e.g. this cannot be kept for another vaccination session as asepsis and sterility could not be guaranteed.

Further information

A factsheet containing information on some of the equipment currently available in connection with vaccine storage and distribution can be accessed at www.telfordccg.nhs.uk/your-health/medicines-management/prescribing-guidelines/vaccines/2233-vaccine-equipment-factsheet/file.

10. Monitoring the fridge temperature

A named / nominated individual must be responsible for monitoring the fridge and ensuring backup systems are in place should the fridge fail. Monitoring of fridge temperature can be delegated to other suitably trained staff providing they understand all aspects relating to this task. This can be facilitated by using the four 'R's'; Read, Record, Reset, React.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

Staff must follow the standard operating procedure for Fridge Temperature (SOP 05.01) which references use of the "Refrigerator and Ambient Room Temperature Monitoring Chart" (Appendix 1).

The refrigerator temperature must be checked and recorded on a daily basis before any of the drugs are used. For clinics which do not operate daily, this should be carried out at the start of each working day.

The following must be monitored and recorded each working day on the "Refrigerator and Ambient Room Temperature Monitoring Chart" (Appendix 1):

- a. The maximum temperature
- b. The minimum temperature
- c. The actual temperature
- d. Action taken if recorded temperature is outside recommendations

The thermometer must be reset after each reading is made. Records must be kept by the fridge.

For clinics / departments using data logging devices e.g. Immunisation Team – the device must be checked daily to ensure the alarm has not been triggered. If the alarm has been triggered, download the information and seek appropriate action for medication stability. If the alarm has not been triggered then the device can be left but a weekly download of information must be done routinely.

Any drug refrigerators where the temperature repeatedly falls outside the limits of 2- 8°C must be reported to the Estates Directorate for maintenance, repair or replacement. If necessary, advice on the status of the drugs can be obtained from the supplying pharmacy or the Shropshire Community Health NHS Trust Medicines Management team. All incidents must be documented and kept by the fridge.

Fridge temperature records will be retained for 5 years.

11. Transporting products e.g. school sessions or domiciliary visits

If a vaccination clinic is being carried out off site, e.g. within a school setting, the vaccine(s) must be transported in the appropriate a validated cool box with minimum and maximum temperature monitoring device. Domestic cool boxes will not be used.

The cool boxes will be ordered by the individual clinics and the vaccines will be packed in accordance to the manufacturer's instructions. Further information can be obtained from

Any unused vaccines from a clinic session which have been stored between 2 - 8°C may be returned to the on-site fridge for future use. They must be marked and dated so that they will be the first stock used at the next session. If a marked vaccine is still unused at the next immunisation session, it should be discarded. If the storage criteria have not been met during a session, stock must not be returned for reuse. To reduce waste, a minimum amount of stock for the minimum amount of time should be removed from the fridge or cold box for use.

Any unused vaccine with a storage condition which falls outside of 2 – 8°C during the clinic session must be discarded in the appropriate clinical waste bin. Refer to section 12.

12. Disposal, including returns and out of date

Vaccines / Fridge-line pharmaceuticals no longer required by clinics must not be returned to the supplying pharmacy, but destroyed using the appropriate pharmaceutical waste disposal bin as per the local Waste Management Policy. Careful consideration should be given to minimising levels of stock held, as unwanted vaccines cannot be returned to stock. Where a 'live' vaccine has been disposed of, ensure this is marked on the outside of the pharmaceutical waste bin.

At the end of an immunisation session any remaining reconstituted vaccine must be placed in the appropriate pharmaceutical waste bin for incineration.

Any out of date, unopened or unfit for use vaccine or fridge line pharmaceuticals, e.g. stored outside required temperature range, should be disposed of in the appropriate pharmaceutical waste bin (some vaccines are classed as 'hazardous waste') according to locality Waste Management contract procedures

Pharmaceutical waste bins are usually yellow with a blue lid. These should be used for expired / unused stock.

Part used vials can be placed into a yellow sharps bin.

BCG Vaccines are classed as cytostatic, therefore, these must be placed in a yellow waste bin with a purple lid. This includes any equipment used during the administration process.

Nursing Homes are individually responsible for disposal of all forms of medical waste produced on the premises; therefore, visiting community teams must not remove any waste.

13. Spillage

Every clinic / ward must have copies of the COSHH safety data sheets of the products used, and a spillage kit.

If spillage of vaccine occurs, gloves should be worn and the spillage soaked up with paper towels immediately.

Any broken glass must be disposed of in a sharps bin and any protective clothing / mopping up equipment placed in a yellow clinical waste bag for incineration.

If appropriate to the product, the area should be cleaned with a chlorine-releasing product, according to Infection Control guidance, (e.g. Presept granules or equivalent product).

Spillage on intact skin should be washed with large amounts of water. Complete an incident form and report to Occupational Health for further medical advice.

Affected eyes should be irrigated well, preferably with sterile 0.9% normal saline. Report to Occupational Health for further medical advice, and complete an incident form.

Chemotherapy spillages must be dealt with using any local procedures ensuring full PPE is worn.

14. Incidents

All incidents involving drug fridges must be reported as per Shropshire Community Health NHS Trust Incident reporting procedures. Ensure when reporting that for the question “Is this a medication incident?” that yes is selected as this will alert the Medicines Management Team that a temperature excursion has occurred and enable them to support the service.

Any drugs refrigerator where the temperature repeatedly falls outside the limits of 2°C - 8°C must be reported to the Estates Department as stated in section 10.

Contingency plans must be in place at each site to cover fridge failure. Plans must contain any reporting requirements, and how to segregate and protect stock.

In all cases the fridge door must be kept closed until a full assessment of the situation has been carried out.

Staff must follow instructions when notified of a “Drug Alert” via the cascade system within Shropshire Community Health NHS Trust, and remove affected batches as per instructions.

15. Training

Maintenance of the cold chain will form part of the immunisation training and update training sessions. However individual / bespoke training around use of fridges, thermometers, and use of the recording paperwork can be available by contacting Shropshire Community Health Medicines Management Team.

All health professionals administering vaccines / other fridge line medicines through a patient specific direction (PSD) or patient group direction (PGD) will have suitable training around the medicines and cold chain policy before being signed off as being competent to administer.

16. Audit

Team Leaders / Ward Managers at each site will be responsible for auditing the following on an monthly basis:

- Daily recording of minimum / maximum and actual fridge and ambient temperatures (or working days where the department does not provide a 7 day service).
- Weekly fridge contents check
- Monthly vaccine stock check

The audit form (Appendix 2), along with an action plan, will be sent to the Chief Pharmacist to provide assurance on the correct storage of medicines.

In addition Shropshire Community Health NHS Trust Medicines Management Team will carry out monthly audits of medicine storage temperatures within community hospitals and prison. The audit, along with temperature monitoring sheets, will be sent to the Chief Pharmacist to provide assurance that medicines are being stored appropriately.

Medicines Management Team will also carry out annual temperature audits for Dental Services, Specials Schools and Children's Community Nursing.

17. References

1. East of England Senior Pharmacy Manager Network (2019) *Recommendations for the Retention of Pharmacy Records* [online] [accessed 7.7.2020] [available at <https://www.sps.nhs.uk/articles/retention-of-pharmacy-records/>]
2. Gov.uk (2006). Health Technical Memorandum 07-01: Safe management of healthcare waste [online] [accessed 7.7.2020] [available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf]
3. Gov.uk (2013), *Immunisation against Infectious Disease. Chapter 3: Storage, distribution and disposal of vaccines* [online] [accessed 7.7.2020] [available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_OW.pdf]
4. NPSA (2010) Rapid response report RRR0-8 *Vaccine Cold Storage* [online] [accessed 7.7.2020] [available at: <https://www.sps.nhs.uk/wp-content/uploads/2018/02/NRLS-1160-Vaccine-Cold-Storage-2010.01.21-v1.pdf>]
5. Telford and Wrekin Clinical Commissioning Group (2016) *Vaccine Cold Chain Standards Policy Version 6* [online] [accessed 7.7.2020] [available at <https://www.telfordccg.nhs.uk/your-health/medicines-management/prescribing-guidelines/vaccines/5741-vaccine-cold-chain-standards-policy-july-2018/file>]

1. **RESET THE THERMOMETER**
2. **Recheck temperature within 1 hour**
3. **Record new temperature and initial the new reading in the same date column**
4. **If temperature is still in the shaded area, further action MUST be taken to safeguard the fridge contents.** For example: bag contents, label and move to another ward medicine fridge, or if not available, a working fridge used for other purposes. Record actions in the grid below.
The Nurse in Charge/Clinic Lead must be informed.
5. **If the fridge is broken, purchase a new fridge via Estates**
6. **Obtain advice from Medicines Management 01743 277 500 to find out if stock is fit to use or email: Shropcom.medicines@nhs.net**

Date	Temperature recorded	Brief note of action, including persons informed

Appendix 2: Medicines Storage Monthly Audit Template

Area / Clinic			
Clinical Lead		Date	
Completed by		Filed by	

	Yes	No	N/A	Comments/Actions
Is Cold chain policy available? SCHAT website	✓			
Is there a fridge failure plan in place? SOP 05.01	✓			
Is there an ambient temperature monitoring and action plan in place?				
Storage Temperatures:				
Fridge temperature recorded daily?				
Any record of fridge temperature being out of range (below 2°C or above 8°C)				
If an "out of range" temperature was recorded what action was taken (add in comments/action)?				
Room temperature recorded daily?				
Any record of room temperature above 25°C? If so what action was taken (add to comments / action column)?				
About the Fridge:				
Vaccine / medicine only?				
Lockable, or in a secure area?				
Uninterrupted electrical supply? Is there a notice on plug "Do not switch off"?				
Evidence of Fridge Cleaning in previous month-check? (check with ward manager if not acknowledged)				
Fridge Maintenance:				
Evidence of maintenance / PAT Test?				
Evidence of stock checks?				
Contents stored correctly?				
Vaccine receipts / log available?				
Disposal guidelines in place?				

Once complete scan to email a copy to Shropcom.medicines@nhs.net

Date sent:

Medicines Storage Temperature Monthly Audit V3 July 2020

Form: MM 006