

**Policy and Procedure for
Maintaining the Vaccine Cold Chain**

For approval by:

The Executive Team

By:

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**Directorate responsible
for Review**

**Screening and Immunisation Team,
Public Health Commissioning**

Signature:

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Directorate	Screening and Immunisation							
Department	Commissioning							
Name of 'activity' being assessed (if possible hyperlink document)	Cold Chain Policy							
	Unique reference number							
Person completing this form	Sue Birchenough							
Lead Manager	Dr Tim Davies							
Date screening completed	2	6	1	1	2	0	1	3
Please indicate (✓) whether activity is Proposed					or Existing			✓
Step One: What is the aim or intended outcome of the activity?								
Aim: To ensure vaccine is transported and stored appropriately.				Outcomes: Those professionals delivering immunisations adopt the policy.				
Step Two: Details of Consultation/Involvement – during the development of this activity?								

CONTENTS

	Page
1. Introduction	5
2. Scope of Policy	5
3. Receipt of Vaccine	6
4. Storage of Vaccine	7
4.1 Refrigerator	8
4.2 Disruption of Cold Chain	9
5. Transporting Vaccines	11
6. Training	11
7. Monitoring and Auditing Arrangements	11
8. References	12
Appendices:	
Appendix 1: Refrigerator Temperature Record Chart	13
Appendix 2: The Vaccine Refrigerator	14
Appendix 3: Decision Tree in the Event of a Cold-Chain Failure	15

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1. Introduction

Vaccines are biological substances that may lose their effectiveness quickly or become potentially dangerous if they become too hot or too cold at any time, especially during transport and storage.

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution (Figure 3.1). Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of +2°C to +8°C until the point of administration¹.

All vaccines must be refrigerated and protected from light. They must **not** be frozen. The efficacy of vaccines depends on their temperature being kept within the range 2-8°C from manufacturer to patient. If storage recommendations are not followed, manufacturers will disclaim responsibility for any subsequent failure of the product. Use of a vaccine that has not been stored correctly is likely to be outside of the licensed use of the vaccine and therefore it cannot be used under a PGD.

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

Public Health England provides a protocol that covers the minimum standards expected of professionals responsible for vaccination².

2. Scope of policy

This policy supports immunisation and vaccination programmes across Leicester City, Leicestershire, Lincolnshire and Rutland. It has been developed to ensure that manufacturers' recommendations are adhered to, in order to protect individual patient care. It should be read in conjunction with the Green Book¹, appropriate Patient Group Directions (PGDs) and Summary of Product Characteristics (SPCs) that are supplied by manufacturers.

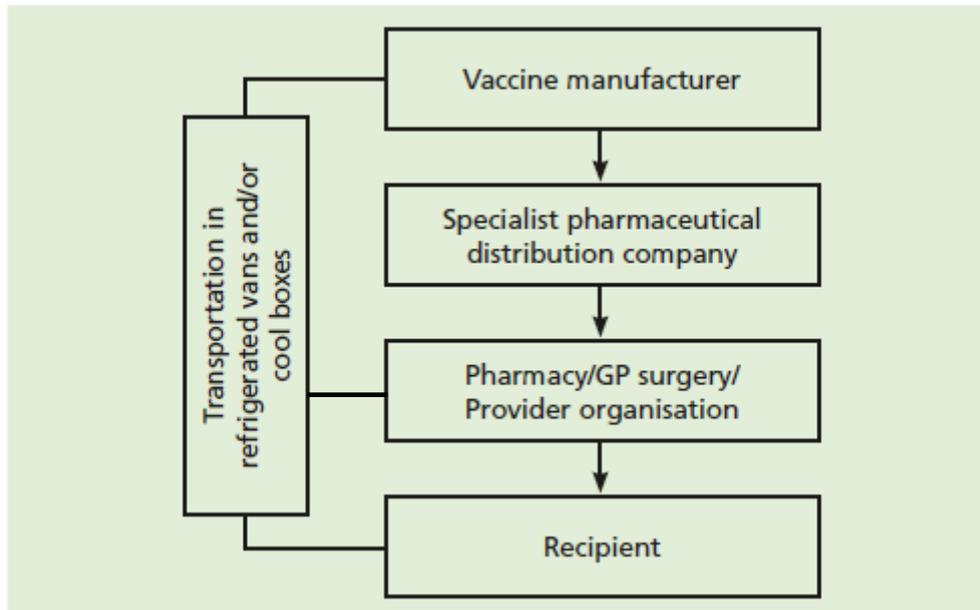
This policy applies to all staff contracted to deliver services on behalf of NHS England.

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

² http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010

3. Receipt of Vaccine

A typical cold chain system for vaccines, taken from the Green Book¹



Named and trained person(s) should be nominated for receiving vaccines.

On receipt of the delivery the designated person(s) should check against the order for discrepancies and for leakage or damage before signing for them. Distributors or manufacturers will not accept items for return once they have left their control.

The following information should be recorded in a separate stock control book:

- Vaccine type and brand
- Quantity
- Batch number and expiry date
- Date and time of receipt
- Signature of person receiving goods

Vaccines must be kept in original packaging and refrigerated immediately on receipt and must not be left at room temperature.

4. Storage of Vaccine

Rotate stock so that those with the shortest expiry date are moved to the front of the refrigerator and used first. Make regular stock-checks to remove expired vaccines. Keep vaccines in more than one fridge where this is possible. Keeping one particular type of vaccine in one fridge is risky and should be spread across more than one fridge if possible.

A stock control book (or database with suitable back-up) should be kept to help maintain the cold chain, as the information will be available without having to open the fridge door for long periods to examine the stock. This record should:

- Keep track of orders, expiry dates and running totals of vaccines.
- Incorporate the refrigerator temperature monitoring chart so that all the information is kept in one place.
- Be dedicated to one fridge – there should be a book for each fridge.

Vaccines used within general practice should usually be used directly from the refrigerator.

If a vaccine session is going to be carried out elsewhere, such as in a school, the vaccine should be transported in an appropriate validated cool box (with minimum and maximum thermometer). The vaccines should be placed quickly into the validated cool boxes and opening must be kept to a minimum. If there are any unused 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 vaccine refrigerator. Returned vaccines should be marked so that they can be used at the earliest opportunity

Vaccines are to be stored in their original packaging at +2°C to +8°C and protected from light, as exposure to ultraviolet light will cause loss of potency. The original packaging is printed with the expiry dates and batch numbers. It protects the vaccine from light, and damage and helps to maintain a consistent temperature. It also contains a patient information leaflet or a summary of product characteristics. Some vaccines have fairly short expiry dates, so do not over-order or stockpile.

All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. Freezing may cause deterioration of the vaccine and lead to hairline cracks in the ampoule, vial or pre-filled syringe which could potentially allow the contents to become contaminated. Patients should not normally be asked to store vaccines, but if they are doing so they should be given clear instructions on safe storage.

4.1 Refrigerator

Temperatures in the fridge are to be monitored and recorded at least once each working day, preferably twice a day and documented as maximum reading, minimum reading and actual reading. The maximum and minimum functions must be reset after each temperature reading. A sample temperature record chart can be found at Appendix 1.

Thermometers will identify when the temperature may have been outside the recommended range. Digital thermometers are the most reliable, preferably those with a probe that goes into the centre of the load. Thermometers, where used, are to be reset and replaced according to the manufacturer's guidance in the centre of the fridge. Fridges that have an external electronic display still need an additional digital thermometer in case of failure of the built-in thermometer or loss of power to the refrigerator (See appendix 2).

Specialised refrigerators are available for the storage of pharmaceutical products, and must be used for vaccines and diluents. **Ordinary domestic refrigerators must not be used.** Food, drink and clinical specimens must not be stored in the same refrigerator as vaccines. Opening of the refrigerator door should be kept to a minimum in order to maintain a constant temperature.

Refrigerators should not be situated near a radiator or any other heat source and should be appropriately ventilated. 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.

All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Either the refrigerator is lockable or the room is locked when not occupied by a member of staff.

Vaccines must never be left unattended once removed from the refrigerator.

Sufficient space is to be provided within the fridge for vaccines to allow for air to circulate freely. The fridge should be no more than 50% full.

Vaccines should be stored on the shelves but not in the compartments on the door or on the floor of the main unit.

Accidental interruption of the electricity supply should be prevented by using a switchless socket or by placing cautionary notices on plugs and sockets.

Ice should not be allowed to build up within the refrigerator, as this reduces effectiveness. The refrigerator should be defrosted regularly in accordance with the manufacturer's guidance.

The refrigerator should be cleaned according to manufacturer's guidelines. Records of regular servicing, calibration, defrosting and cleaning should be

kept. This can be logged on the refrigerator temperature chart (please see Appendix 1).

It is strongly advised that suitable facilities such as a spare fridge or a cool box are available in the event of a fridge failure.

4.2 Disruption of Cold Chain

In the event of cold chain failure the following will apply:

- Check the temperature inside the fridge and try to ascertain how long it has been without power
- Remove all vaccines to another working refrigerator or storage box until you can confirm whether or not they can be used. Make sure they are labelled accordingly.
- Do not use any vaccine that has been out of the cold chain until advice has been sought from the manufacturer.
- Check the plug. Ensure it hasn't been disconnected.
- Check whether the failure is due to a short term electricity failure. Do you have a backup facility such as a generator and is it working?
- Inform the person designated to be in charge of all the refrigerators or a manager, in their absence, so that a repair engineer can be called.
- Inform your immunisation co-ordinator in the screening and immunisation team on 0113 824 9515. The vaccine may be usable even when there has been a cold chain failure.
- Make a list of all the vaccines affected and gain advice following a cold chain breach from local Medicines Information Services:
 - Leicester Royal Infirmary, telephone 0116 258 6491 or 0116 204 7918, e-mail medicines.info@uhl-tr.nhs.uk
 - Lincoln County Hospital, telephone 01522 573802, e-mail medicines.information@ulh.nhs.uk
- Complete the stock incident form on vaccine supply section of the ImmForm website using your own login and password:
<https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2fVaccineSupply%2fVaccineSupply%2fStock-Incident%2fAdd-Stock-incident.aspx>
- The vaccine manufacturers
 - Glaxo Smith Kline on (0808) 100 9997

- Sanofi Pasteur on (01628) 587693
- Novartis on (08457) 451500
- Baxter Healthcare on (01635) 206345

The following information should be given:

- The maximum period of cold chain disruption.
- The actual, minimum and maximum temperature readings recorded on the thermometer.
- What the vaccines are.
- When the next immunisation session is.
- Which of the vaccines are required urgently.

Arrange for vaccines to be returned to correct storage conditions immediately and if it is advised that vaccine may still be used, mark and ensure that these vaccines are used first. Practice insurance may cover practice-purchased vaccines but not DH supplied vaccines

- Once the vaccine fridge is working again the correct temperature maintained, replace the vaccines. Any stock destroyed should be replaced with new stock.
- All failures to be recorded and the reasons for the failure to be entered into the record book. A critical incident report should also be completed.

Follow the guidance on managing cold chain incidents as produced by Public Health England or see appendix 3.

5. Transporting Vaccines

Suitable rigid containers will be used at all times to reduce damage to vaccines during transit and maintain temperature. Domestic cool bags should not be used to store, distribute or transport vaccines. Validated cool boxes (with maximum-minimum thermometers) and cool packs from a recognised medical supply company should be used. Individual manufacturers' instructions should be strictly adhered to (check with Electronic Medicines Compendium (EMC) for Summary of Product Characteristics³).

Vaccine to be kept in original packaging, (or similar insulation material) and placed into a cool box with cool packs wrapped in bubble wrap or as recommended by the manufacturers' instructions. This will prevent direct contact between the vaccine and cool packs and will protect the vaccine from damage, such as being frozen.

Cool packs should be used whenever possible. These must be insulated to prevent direct contact with the vaccine. They should be placed in the bag in accordance with manufacturers recommendations. They must not come into direct contact with the vaccine. Space within the container must be loosely filled to minimise circulating air.

Cool boxes and packing material should be stored at the lowest temperature possible prior to packing with the vaccine load and vaccine should be loaded as late as possible before departure to minimise exposure time out of the fridge.

On arrival at the vaccination session, vaccines should be transferred to a refrigerator if available. Otherwise they must be left in the closed cool box until they are required. Where vaccines are to be stored overnight, a dedicated vaccine fridge or an electric portable storage unit that maintains the correct temperature can be used. The unit is to be kept in a secure location and the vaccine to be used first the following day.

6. Training

Cold chain compliance must be incorporated into immunisation and vaccination training.

7. Monitoring Arrangements

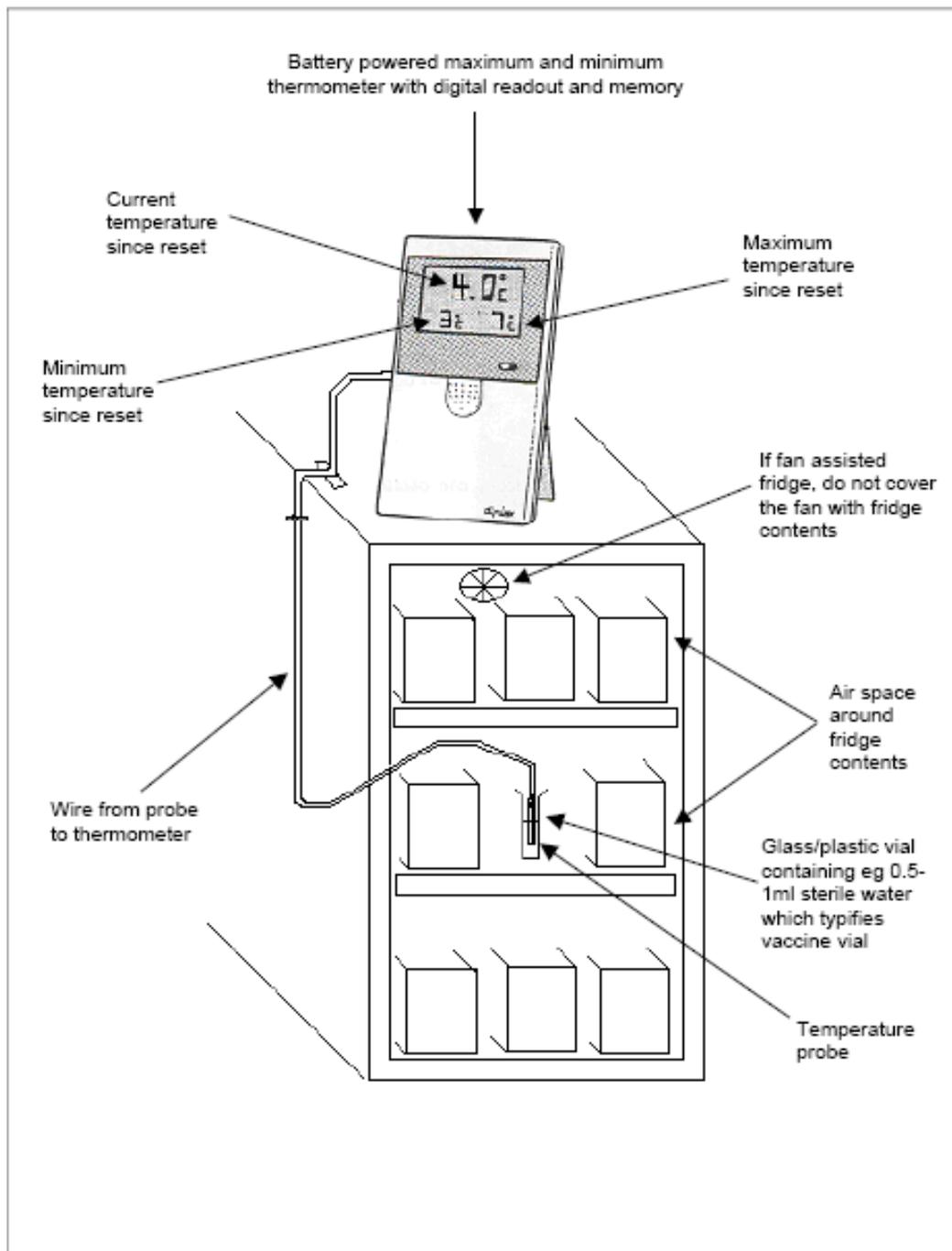
The effectiveness of this policy and procedure will be reviewed on a two-yearly basis, and sooner, subject to changes in legislation. The review will be undertaken by the Lead Officer(s) for Immunisation within the NHS England Area Team.

³ <http://www.medicines.org.uk/emc/default.aspx>

8. References

- Department of Health. 2006. Immunisation Against Infectious Disease (The Green Book, current edition)
<https://www.gov.uk/government/publications/green-book-the-complete-current-edition>
- Electronic Medicines Compendium (EMC) for Summary of Product Characteristics
<https://www.medicines.org.uk/emc/>
- Public Health England (former Health Protection Agency). Core Topic 8. Storage and Handling of Vaccine.
<https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
- Public Health England (former Health Protection Agency). Vaccine incident protocol
http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551139589
- Department of Health guidance on the safe storage and handling of vaccines
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010

Appendix 2 The Vaccine Refrigerator



Source: The vaccine cold-chain from manufacturer to patient (guidance on the storage and transport of vaccines, North Yorkshire HPA, April 2006).

Appendix 3

Decision Tree in the Event of a Cold-Chain Failure

