

# **POLICY FOR MAINTAINING THE COLD CHAIN FOR VACCINES**

**REF PC/002/1/06**

**APRIL 2006**

## Policy Reference Information

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## Document Revision Record

<b>Version</b>	<b>Description of Change(s)</b>	<b>Reason for Change</b>	<b>Author</b>	<b>Date</b>
1	New policy – for a risk area identified during practice visits	No current policy in place	Rozalia Enti	March 2006

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## Policy for Maintaining the Cold Chain for Vaccines

### 1. INTRODUCTION

Vaccines are biological substances that may lose their effectiveness quickly and permanently if not maintained within the cold chain i.e. maintenance within manufacturer's storage temperatures (typically +2 to +8<sup>0</sup>C) during transport and storage.

Inadequate temperature control during storage and transport of vaccines can reduce the efficacy of the vaccine and compromise attainment of a satisfactory level of immunity. Freezing can cause deterioration of the vaccine. It can also produce hairline cracks in the ampoule/vial/pre-filled syringe, potentially contaminating the contents. Glass speckles produced may also cause serious local adverse reactions.

### 2. REFERENCES

1. Immunisation against Infectious Diseases, HMSO. (Greenbook)  
Chapter 4 Storage, distribution and disposal of vaccines November 2005  
<http://www.dh.gov.uk/assetRoot/04/12/33/46/04123346.pdf>
2. UK Guidance on Best Practice in Vaccine Administration 2001  
[http://www.rcn.org.uk/publications/pdf/guidelines/rcn\\_vaccine\\_uk\\_guidance.pdf](http://www.rcn.org.uk/publications/pdf/guidelines/rcn_vaccine_uk_guidance.pdf)

### 3. POLICY STATEMENT

This policy outlines the PCT recommendations on handling, storage and disposal of vaccines. Its aim is to ensure the efficacy of vaccines is maintained in all NHS settings within Newham PCT and to support general practices in fulfilling the contractual and statutory requirements of the new General Medical Service (GMS) contract in relation to the storage and handling of vaccines.

Every practice and community clinic within Newham PCT is expected to implement the standards within this policy and to:

1. have one trained individual with at least one trained deputy responsible for the receipt and storage of vaccines and the recording of refrigerator temperatures [practice's named designated person / position]
2. ensure that all staff involved – at any level – with the receipt, transportation and administration of vaccines or monitoring of fridge conditions are familiar with the standards outlined and their role in ensuring the efficacy and safety of vaccines are maintained.
3. undertake a regular – at least **annual** – audit of cold chain practices.

Practice and clinic managers must ensure that all staff members are:

- made aware of the risks pertaining to improper storage and handling of vaccines
- familiar with the standards within this policy
- able to seek advice from appropriate persons if breaches in the maintenance of the cold chain are suspected

The policy is based on recommendations made by The Department of Health and UK Guidance on Best Practice in Vaccine Administration.

## 4. ORDERING

- 4.1 The practice / clinic / health centre must maintain stock levels appropriate to their usage and avoid over ordering and stockpiling.
- 4.2 The practice /clinic/ health centre must have a designated suitably trained staff member [named designated person / position], and a deputy to cover absences, responsible for stock control and ordering.

## 5. RECEIPT

- 5.1 All members of staff (including reception and temporary staff) must be aware of the importance of maintaining the cold chain. They must know the location of the vaccine fridge and have access to it at all times so as to store delivered vaccines.
- 5.2 On receipt, vaccines must be checked for leakage or other damage before signing for them. Pharmaceutical distributors and manufacturers will not accept any vaccine for return once it has left their control. The vaccines must then be placed in the designated fridge immediately. Care must be taken not to mix newly delivered vaccines with 'older' stock.
- 5.3 The designated person must be informed of the delivery immediately.
- 5.4 The designated person must ensure the vaccine delivery is stored according to the manufacturer's recommendations.
- 5.5 The vaccines must be checked off against the delivery sheet. The vaccine type, brand, quantity, batch numbers and expiry dates must be recorded with the date and time at which they were received. In the event of a discrepancy, contact the supplier.
- 5.6 The practice / clinic must keep a record of all vaccines received, their batch numbers and expiry dates. The completed, signed delivery sheet must be retained for 2 years.

## STORAGE CONDITIONS

### 6. REFRIGERATORS (FRIDGES)

- 6.1 **The fridge in which vaccines are stored should be specifically designed for safe storage of vaccines.** Domestic or 'food' refrigerators must **NOT** be used to store vaccines as the temperature of these fluctuates considerably. (See Appendix 1 for information source for suppliers of suitable fridges)
- 6.2 The fridge should be dedicated to storing only vaccines and other pharmaceutical products that require storage below 8<sup>0</sup>C. Food, milk, drinks, specimens must **NOT** be stored in the vaccine refrigerator. The recommendations for not storing clinical specimens in the vaccine fridge are stated in Department of Health

guidance. The PCT does not support routine use of vaccine fridges to store specimens but acknowledges that there may be occasions when this may become necessary. In such instances the specimen container should be secured tightly and enclosed in a heat or self sealed plastic bag and placed in the bottom draw of the fridge where vaccines must never be stored.

- 6.3 All fridges must be lockable or in a locked room. Vaccines must never be left unattended at outlying clinics.
- 6.4 The fridge must not be sited in front of a radiator or any other heat source.
- 6.5 The fridge plug should be wired directly into switch-less sockets to avoid accidental disconnection. If this is not possible, then the plug should be taped over and labelled with a cautionary notice.
- 6.6 A vaccine fridge's capacity is not how many packs of vaccines can be physically fitted onto the shelves. The contents should be evenly distributed within the fridge to allow air to circulate. There must be enough space within the fridge to hold the necessary stock as well as for air to circulate freely around the vaccine packages and the back of the fridge, thus enabling the temperature to remain constant.
- 6.7 The fridge must not be overfilled. If the fridge is overfilled this reduces, and may stop, air circulation in fridge, thus affecting the fridge temperature. Stockpiling, particularly in small fridges, also hinders stock rotation.
- 6.8 If large quantities of vaccine are required e.g. during flu campaigns it may be necessary to increase the frequency of ordering rather than the quantity per order, in order to maintain safe storage systems.
- 6.9 In under filled fridges, using a container (e.g. plastic container with a lid) filled with water will act as a barrier to warm air entering the fridge and help reduce temperature fluctuations.
- 6.10 Fridge door opening must be kept to a minimum.
- 6.11 Vaccines must not be stored in the door of the fridge, as the temperature here is warmer than in the main interior of the refrigerator. Vaccines must not be stored in the bottom drawers or adjacent to the freezer plate of the fridge where temperature variations to the recommended +2<sup>0</sup>C to +8<sup>0</sup>C are more likely to occur.
- 6.12 The fridge should be regularly cleaned – at least **monthly** – and a record of cleaning must be maintained by a designated person. Any out of date vaccines should be disposed of in a sharps bin.
- 6.13 The fridge must be defrosted regularly e.g. every **6-8 weeks** if the fridge is not self defrosting. Ice should not be allowed to build up within the fridge as this reduces effectiveness. Vaccines must be transferred to another drug / vaccine

fridge or cool box with pre cooled ice packs while defrosting takes place. The temperature of the temporary storage place of the vaccines must be monitored to ensure the cold chain is maintained. After defrosting, vaccines should only be replaced once the original fridge has returned to the correct temperature. Records of dates and times of defrosting must be kept.

- 6.14 The fridge must be serviced regularly - **at least annually** - and records of servicing reports and remedial actions kept.

## 7. THERMOMETERS

- 7.1 The fridge should have an independent maximum/minimum thermometer which also records the actual temperature, even if there is an integral thermometer or an external temperature indicator dial. Digital thermometers are the easiest to read and reset and the most reliable.
- 7.2 The thermometer should be in the centre of the main body of the fridge.
- 7.3 Such thermometers may be purchased from reputable laboratory suppliers some of whom are able to provide a certificate of conformance/calibration.  
(See Appendix 1 for information source for suppliers of suitable thermometers)
- 7.4 The calibration of thermometers should be checked **annually** to ensure that they are working correctly. Record of the annual calibration should be readily accessible for easy reference and retained until the next audit.

## 8. MONITORING

- 8.1 A named individual and named deputy should be responsible for monitoring the cold storage of vaccines.

The following should be monitored and recorded each working day i.e. Monday to Friday

- A) The **maximum** temperature
- B) The **minimum** temperature
- C) The **actual** temperature

(see Appendix 2)

- 8.2 The thermometer must be reset after each reading is made. All staff members involved in fridge temperature monitoring must know how to reset the thermometer.
- 8.3 Any refrigerator temperature reading falling outside the limits of +2 to +8<sup>0</sup>C (less than +2<sup>0</sup>C or higher than +8<sup>0</sup>C) must be reported to the designated lead responsible for storage of vaccines (e.g. Practice Nurse) immediately to ensure appropriate action is taken.

The designated person should try to ascertain how long the temperature has been out of range and then seek advice on which if any vaccines can still be used.

- Practices:- The designated person in practices should contact the PCT's Medicines and Prescribing department. Telephone: 020 8271 1322
- Community clinics:- The designated person in Community clinics should contact the community services technician on 020 7363 8046 (Pharmacy, Newham University Hospital NHS Trust)

See Appendix 3 for an example of minimum information that the practice / clinic is required to document and that the PCT or Community services technician will require.

- 8.4 Where a fridge has been found to be malfunctioning or the fridge thermometer reading falls outside the limits of +2 to +8<sup>0</sup>C or vaccines have not been stored according to the manufacturers' recommendations, the practice / clinic must record this on a serious untoward incident form and report this incident as per the practice's / clinic's clinical governance procedures.
- 8.5 Vaccines should be stored in the manufacturer's packaging as this is printed with the batch number and expiry date and protects the vaccine from damage from light. It also contains important product information as well as the patient information leaflet that must be given to the patient at the time of administering the vaccine.
- 8.6 There should be no out of date stock stored in the fridge. Out of date stock must be disposed of by placing the vaccines directly into a sharps disposal bin.
- 8.7 It is essential that vaccines are used in order of shortest expiry date first. Stock should be rotated according to expiry date and older stock positioned at the front of the fridge and newest stock stored to the rear of the fridge. A record of short dated stock must be maintained by a designated person.
- 8.8 The community infection control team will check the vaccine storage conditions in use at their annual visit to practices and will expect to see an appropriate refrigerator is in use and that daily fridge temperatures are being documented appropriately. Failure to provide appropriate evidence will result in this being highlighted as high risk in the subsequent report and may lead to further action by the PCT in respect to frequency of monitoring or contractual action for resolution.
- 8.9 The new GMS contract requires practices to have systems in place to ensure regular and appropriate inspection, calibration and replacement of equipment including: a defined responsible person, clear recording, systematic pre-planned schedules and reporting of faults. Practices should be able to provide a written record of inspection, calibration and maintenance for their vaccine fridges as part of the requirements for this indicator during the PCT's annual QoF visits to practices.



- 8.10 Practice's adherence to the standards within this policy will also be monitored through the Medicines and Prescribing department's repeat prescribing audit. Findings of inadequate standards may lead to further action by the PCT in respect to frequency of monitoring or contractual action for resolution.

## **9 MAINTENANCE OF THE COLD CHAIN DURING CLINICS AND DOMICILIARY VISITS**

- 9.1 Vaccines kept for prolonged periods at high temperatures are rendered ineffective and can develop dangerous toxins. It is the cumulative effect of exposure to temperatures above those recommended by the manufacturer that reduces potency. Numerous short occasions at higher temperatures are as detrimental as one long period of time.
- 9.2 Vaccines should never be left out of refrigeration. Vaccines needed for sessions in outlying clinics or home visits should be transported in an appropriate validated cool box with a thermometer obtained from a recognised medical supply company. (See Appendix 1 for information on obtaining validated cool boxes). Individual vaccine manufacturers' instructions must be strictly adhered to.
- 9.3 Care should be taken to keep frozen ice packs out of direct contact with the vaccine as this can cause the product to freeze. Freezing may cause deterioration of the vaccine and cracking / breakage of the container. Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into the cool box with cool packs as recommended by the manufacturer.
- 9.4 Any unused vaccines may be returned to the fridge as soon as possible after the session, marked and dated so that it will be the first stock used at the next session. If the storage criteria have not been met, stock must be disposed of and not be returned for reuse. To reduce waste, a minimum amount of stock should be removed from the fridge at each time and for the shortest period possible.
- 9.5 During immunisation sessions within practices / clinics, vaccines can be transferred to a cool box to prevent frequent opening of the refrigerator door.
- 9.6 Patient held vaccines' should be discouraged as the cold chain is interrupted. Where patients require non routine vaccines, the patient should take the prescription to a nearby community pharmacy then either:
- the surgery collects the vaccine from the pharmacy for storage in the practice's vaccine fridge or
  - the pharmacy delivers the vaccine to the surgery or
  - the pharmacy stores the vaccine until needed and the patient collects the vaccine from the pharmacist and brings the vaccine into the surgery straight away for administration.

Practice's cannot normally direct patients to specific pharmacies however this advice to use a pharmacy local to the practice is to minimise breaks in the cold chain.

## 10. TRANSPORT

- 8.1 A validated cool pack/box must be used for transporting vaccines requiring cold storage (see points 9.1-9.5 above & Appendix 1).
- 8.2 The time between removing vaccines from cool storage and use must be kept to a minimum.

## 11. DISPOSAL

- 11.1 Single dose containers are preferable. Reconstituted vaccine must be used within the manufacturer's recommended period. At the end of an immunisation session, any remaining reconstituted vaccine or opened multi-dose vials should be placed in a sharps bin for incineration.
- 11.2 The sharps bin should be replaced once it is two-thirds full and should not be accessible to any unauthorised individual.
- 11.3 Any out of date unopened vaccine or vaccine unfit for use i.e. stored outside required temperature range should be disposed of in a sharps bin for incineration.

## 12. SPILLAGE

- 12.1 The area should be cleaned according to the manufacturer's guidance for vaccine spillage.
- 12.2 The practice / clinic should have copies of the COSHH safety data sheets for each vaccine used. These data sheets provide information on how to deal with spillages/breakages and are available from the vaccine manufacturers.
- 12.3 Vaccine spillages must be dealt with immediately. Protective clothing e.g. gloves should be worn and the spillage soaked up with sodium hypochlorite solution providing at least 1% available chlorine (e.g. Milton®, Sanichlor® or equivalent) and paper towels followed by a clean with water. Care must be taken to avoid skin puncture from glass or needles. Contaminated materials must be destroyed by incineration.
- 12.4 Spillage on skin should be washed with soap and water.
- 12.5 Affected eyes should be washed preferably with sterile 0.9% normal saline and occupational health advice sought.

## 13. INCIDENTS

- 13.1 Any vaccine refrigerator temperature falling outside of the limits of +2 to +8<sup>0</sup>C must be reported to the designated lead responsible for storage of vaccines (e.g. Practice Nurse) immediately to ensure appropriate action is taken.

- 13.2 If there are concerns about storage or potency of vaccines (due to suspected or proven fridge/thermometer malfunctioning or fridge thermometer reading falls outside the limits of +2 to + 8<sup>0</sup>C or vaccines have not been stored according to the manufacturer's recommendations) guidance on use of affected vaccines should be sought from the relevant department as stated below:
- Practices should contact the PCT's Medicines and Prescribing department. Telephone: 020 8271 1322
  - Community clinics should contact the Community services technician on 020 7363 8046 (Pharmacy, Newham University Hospital NHS Trust)
- 13.3 The designated person must try to ascertain how long the temperature has been out of range. See Appendix 3 for an example of minimum information that the practice / clinic is required to document and that the PCT or community services technician will require.
- 13.4 Where a fridge is suspected to be malfunctioning, or the fridge thermometer reading falls outside the limits of +2 to+8<sup>0</sup>C practices must contact, immediately, the fridge manufacturer or the servicing company recommended by the fridge manufacturer. It is important that practices use a servicing company that has been approved by the fridge manufacturer in line with the terms and conditions of the fridge's guarantee or warranty. Community clinics should contact the PCT's Estate and Facilities Helpdesk on 020 8586 6441 immediately.
- 13.5 All incidents of:
- fridge or thermometer malfunctioning or
  - fridge thermometer readings outside the limits of +2 to +8<sup>0</sup>C or
  - vaccines not stored according to the manufacturers recommendations must be recorded on a serious untoward incident form and reported as per the practice's / clinic's clinical governance procedures.
- 13.6 Practices and clinics must follow instructions from the Department of Health or the PCT when notified of a vaccine "Drug Alert".

## INFORMATION SOURCES

1. Immunisation against Infectious Diseases, HMSO. (Greenbook)  
Chapter 4 Storage, distribution and disposal of vaccines November 2005  
<http://www.dh.gov.uk/assetRoot/04/12/33/46/04123346.pdf>
2. UK Guidance on Best Practice in Vaccine Administration 2001  
[http://www.rcn.org.uk/publications/pdf/guidelines/rcn\\_vaccine\\_uk\\_guidance.pdf](http://www.rcn.org.uk/publications/pdf/guidelines/rcn_vaccine_uk_guidance.pdf)
3. Patient Group Directions (PGD) for individual vaccines
4. Medicines Information Department: Newham University Trust Hospital  
Telephone number: 020 7363 8048.
5. Medicines Information Departments of individual vaccine manufacturers
6. Individual vaccine Summary of Product Characteristics (SPC).  
<http://www.medicines.org.uk>

## **APPENDIX 1**

Updated advice on suppliers of refrigeration equipment including refrigerators, thermometers and cool boxes is available from:-

Health Protection, International Health and Scientific Development- Immunisation Policy  
Department of Health  
Area 512  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG

Telephone:- 020 7972 1227

**Validated Cool Boxes** – e.g. Mini Vaccine Porter® (other sizes available)

- Used for transportation of vaccines
- Hold up to 10 vials of vaccine
- Maintain the temperature within the system between 2°C and 8°C for 18 hours

Further information on Vaccine Porter® available from:

CliniMed  
Cavell House  
Knaves Beech Way  
Loudwater  
High Wycombe  
Bucks  
HP10 8QY

Tel: 01628 850100  
Fax: 01628 527312  
E-mail: [enquiries@clinimed.co.uk](mailto:enquiries@clinimed.co.uk)  
Website: <http://www.clinimed.co.uk>  
CareLine: 0800 0360100

**APPENDIX 2 - FRIDGE MONITORING SHEET**

Practice/ Clinic.....MONTH.....YEAR.....

DESIGNATED STAFF.....  
RESERVE STAFF.....

Please record temperature at least DAILY (Mon-Fri). Ensure fridge is cleaned regularly.

If the refrigerator temperature readings are outside the required range (+2° to +8°C), please check the points in the guidelines section and contact the PCT or community services technician. It is also recommended that you complete an Incident form.

LOCATION OF FRIDGE .....

DATE	TIME	ACTUAL	MAXIMUM	MINIMUM	INITIALS	Thermometer Reset? Y/N	Troubleshooting
1							<ul style="list-style-type: none"> <li>• Has the fridge been disconnected / turned off / or has there been a power cut?</li> <li>• Has the fridge door been left open?</li> <li>• Has the fridge been opened frequently in the last few hours or was there a session the previous day?</li> <li>• Is the thermostat set too high or too low? (if applicable)</li> <li>• Was the thermometer reset correctly after the last reading?</li> <li>• If used, is the temperature probe correctly placed in a bottle of water inside the fridge?</li> <li>• Is the fridge more than half full?</li> <li>• Does the fridge need defrosting?</li> <li>• Has the thermometer been accidentally damaged e.g. fallen off the fridge?</li> <li>• Does the fridge need servicing?</li> </ul>
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FRIDGE CLEANED ON.....FRIDGE DEFROSTED ON.....

**Records must be kept for 2 years.**

**APPENDIX 3 - VACCINE FRIDGE INCIDENT FORM**

<b>Person reporting incident:-</b>	<b>Person filling in form</b>
<b>Contact telephone number:-</b>	<b>Time call taken</b>
	<b>Date</b>

		Details
1	Practice / Clinic Name & Address	
2	Position of Reporter of Incident	
3	Details of incident	
4	What is the current temperature showing	
	What is the minimum temperature	
	What is the maximum temperature	
5	Which fridge is affected	
6	How long has the fridge been malfunctioning	
7	When – day & time –were the last correct temperatures recorded	
8	When is the next vaccination session	
9	Which vaccines are urgently required	
10	Where will these vaccines come from	
11	Other comments	

**FEEDBACK ON COLD CHAIN POLICY**

We would be very keen to hear your feedback on the Cold Chain Policy. If you have any comments, please fill in the form below and fax it back to 020 8271 1335 for the attention of Gemma Cassidy or email your comment to [gemma.cassidy@newhampct.nhs.uk](mailto:gemma.cassidy@newhampct.nhs.uk)

Thank you in anticipation for your help.

***Comments on the content***

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***Any suggestions for additions that can be made to future revised versions of this policy?***

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***Any other comments?***

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Name:.....

Position:.....

Workplace:.....

(Giving these details is optional)