Guidelines on the Storage and Handling of Vaccines and Other Medicines Requiring Cold Storage

‘The Cold Chain’

NICE GUIDANCE
Once NICE guidance is published, health professionals are expected to take it fully into account when exercising their clinical judgment. However, NICE guidance does not override the individual responsibility of health professionals to make appropriate decisions according to the circumstances of the individual patient in consultation with the patient and/or their guardian or carer.
Version Control

Current versions of all Locala Community Partnerships CIC (LCP) policies can be found on the NHS Kirklees website under the Locala section. If printing a document, please check for the most up-to-date version.

<table>
<thead>
<tr>
<th>Primary Circulation List:</th>
<th>All LCP employees involved in immunisation and vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web address:</td>
<td><a href="http://www.kirklees.nhs.uk/your-health/medicines-management/locala-policiesguidelines/">http://www.kirklees.nhs.uk/your-health/medicines-management/locala-policiesguidelines/</a></td>
</tr>
<tr>
<td>Restrictions:</td>
<td>This document is provided for use by LCP staff. Other healthcare professionals providing healthcare services within Locala Community Partnerships geographical area may use this document as a source of guidance and reference to local practice and procedures</td>
</tr>
</tbody>
</table>

Standard for Better Health Map

<table>
<thead>
<tr>
<th>Domain:</th>
<th>First Domain: Safety</th>
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<tbody>
<tr>
<td>Core Standard Reference:</td>
<td>C4d</td>
</tr>
<tr>
<td>Performance Indicators:</td>
<td>1. Healthcare organizations keep patients, staff and visitors safe by having systems to ensure that medicines are handled safely and securely.</td>
</tr>
</tbody>
</table>
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POLICY STATEMENT
Locala Community Partnerships Community Interest Company (LCP) will endeavour to ensure the safe and secure handling of medicines to protect patients, staff and the public in accordance with current legislative requirements and best practice.

1. Introduction

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.

Any medicine stored outside the temperature range specified by the manufacturer is no longer a licensed product.

All vaccines have a predetermined shelf life and the potency of vaccines is guaranteed by the manufacturers up to the expiry date as stated on the product, if stored within the safe temperature range of between 2ºC and 8ºC.

This policy applies to all healthcare staff handling or administering vaccines within LCP. It is also good practice to refer to, and follow guidance in this policy for all medicines requiring refrigerated storage.

This guidance should also be read in conjunction with the Department of Health’s ‘Immunisation Against Infectious Diseases’ 2006 (The Green Book) and the UK Guidance on Best Practice in Vaccine Administration 2001.

2. Associated Policies & Procedures

This policy should be read in accordance with the following LCP policies, procedures and guidance:

- Medicines Management Policy
- Waste Management Guidelines
3. **Aims and Objectives**

The aim of this document is to provide guidance to all staff who handle or administer vaccines on the safe storage and distribution of vaccines. It is essential that all those handling vaccines follow policy to ensure cold chain compliance.

4. **Scope of the Policy**

This policy **MUST** be followed by all LCP employees involved in immunisations and vaccinations.

It **MUST** be followed by all staff working for LCP including those on temporary or honorary contracts, bank staff and students.

Breaches of this policy may lead to disciplinary action being taken against the individual.

Independent Contractors are responsible for the development and management of their own procedural documents and for ensuring compliance with relevant legislation and best practice guidelines. Independent Contractors are encouraged to seek advice and support as required. It is recommended this policy should be used as guidance to ensure that the appropriate policies and procedures for the safe and secure handling of medicines with their area of practice are in place.

5. **Accountabilities and Responsibilities**

All staff involved with immunisations and vaccinations, or in the storage of other medicines requiring cold storage, must familiarise themselves with the correct procedures contained within this policy.

Those in charge of services are responsible for ensuring that their staff, particularly new starters and locums, follow procedures in this policy. Hard copies of the policy will be available to all staff through service leads and line managers. An electronic version is available under the [Locala section](#) of the NHS Kirklees website.

The procedures also apply to staff from other NHS Trusts or private practices, who are contracted to work for LCP on a sessional basis. Managers who contract for these services must make it explicit within the written contract that these sessional staff **MUST** follow the procedures described in this policy.
All professionals are required to work within their Professional Code of Practice and terms of service.

6. What is the Cold Chain?

The term cold chain is the name given to the system of transporting and storing vaccines within the safe temperature range of between 2°C and 8°C.

The success of any immunisation programme depends on administering effective vaccines. Vaccines quickly lose effectiveness if they get too hot or cold during transport and storage. It is therefore essential to maintain an unbroken cold chain for the vaccines from the point of manufacture, during transport and during storage in a refrigerator until they are used to vaccinate someone.

The cold chain involves all the people, equipment and procedures which ensure that an effective vaccine reaches the people who need it.

7. Delivery, Storage and Stock Control

All vaccines have a predetermined shelf life and expiry dates are clearly marked on the outer packaging of each product.

The expiry date is dependent upon the vaccine being stored in the correct manner and maintenance of the cold chain throughout the shelf life of the product. Breaks in the cold chain may result in loss of potency of a vaccine and ultimately to vaccine failure.

To achieve an effective immunisation programme, adhere to the manufacturer’s recommendations regarding storage at all times.

At each clinic, health centre, surgery or pharmacy, a suitably trained member of staff should be nominated to be responsible for checking the vaccines and looking after the refrigerator. There must be at least one deputy assigned to cover times of absence. The designated persons must be competent in reading and resetting the maximum/minimum thermometer and must take appropriate action upon discovering any variation in temperature from the parameters of 2°C to 8°C. Their names should be clearly displayed on the refrigerator door.
Any other staff who may be involved with vaccines must also be trained appropriately.

Reception staff receiving deliveries must be aware of the importance of ensuring that vaccine deliveries are handed over to the person responsible for them, as soon as possible. They should also know what action to take if that person (or their deputy) is unavailable.

The designated person who receives a vaccine delivery must observe the manufacturer's recommendations on storage. Care should be taken to ensure that vaccines are checked for leakage or other damage and immediately placed under the required storage conditions in the vaccine refrigerator.

Ideally patients or parents should not be asked to store vaccines.

8. Refrigerators
All vaccines are Prescription Only Medicines (POM) and must be stored under locked conditions and the keys stored securely.

The refrigerator should be designed specifically for storage of pharmaceuticals or vaccines.

Refrigerators must be reserved exclusively for the storage of vaccines and other drugs that require storage between 2°C and 8°C. Do not store food, milk, drink or specimens in the vaccine refrigerator.

The refrigerator should be large enough to hold the necessary stock and allow sufficient space around the individual vaccine packages for air to circulate, thus enabling the temperature to remain constant.

If large quantities of vaccine are required, (e.g. during the flu season), it may be necessary to increase the frequency of ordering, rather than the quantity ordered, to avoid receiving more than can be stored safely.

Vaccine refrigerators should be wired into switch-less sockets to avoid them being switched off accidentally. If this is not possible, tape over the plug and label with a cautionary notice.
Do not store vaccines in the door of the refrigerator, as the temperature is warmer than in the main body.

**DO NOT FREEZE VACCINES.** Freezing may inactivate the liquid vaccines and can cause the glass ampoules to crack. Any vaccine subjected to temperatures of 0°C and below must be discarded.

Keep vaccines away from the freezing compartment, cooling element or panel where ice may form and direct contact with frozen ice packs. Defrost the fridge regularly to prevent build up of ice, which can cause the temperature to drop below 0°C.

Advice on suppliers of refrigeration equipment and cool boxes is available from the Medicines Management Team on 01924 351525

9. **Recording and Monitoring**

The correct temperature of the vaccine refrigerator is between 2°C and 8°C. Aim for 5°C, as this gives a safety margin of + or – 3°C.

The fridge must have a maximum and minimum thermometer, which also records the current temperature. All fridges should ideally have two maximum/minimum thermometers, with one independent of mains power. If only one thermometer is used, then a regular/monthly check should be carried out to confirm that the calibration is accurate.

For maximum/minimum thermometers, which use a probe, this should be positioned in the centre of the fridge, among vaccines, not near the ice box or the door seal.

The named person and deputy at each base should be nominated to read and record the maximum, minimum and current temperature at the beginning of each working day. The thermometer must always be reset after recording each reading.

**PLEASE NOTE:** When the CURRENT fridge temperature reading is outside the recommended range of 2°C and 8°C, it is important to ensure the current temperature is back within the normal 2°C and 8°C range before resetting.

If the thermometer is reset with a high or low current temperature reading, this ‘out of range’ reading will be stored as the maximum or minimum reading until the next reset.
If this happens at the end of the working week, the next temperature reading will appear to indicate the fridge has been out of range for anything up to 72 hours. Advice provided relating to cold chain breaks is always based upon the last ‘in range’ reading, so in this situation the contents of the fridge would have to be destroyed.

The temperatures must also be checked before removing any vaccine or before an immunisation session starts, to ensure the correct temperature range has been maintained.

The LCP temperature recording sheet (appendix C) must be used for all LCP premises and a copy faxed to the number stated on the bottom of the form at the end of each month. Independent Contractors are responsible for the development and management of their own procedural documents but are encouraged to follow this guidance as best practice. Fridge temperature monitoring records should be kept for 2 years.

Both the nominated person and the deputy must have training in the principles of the cold chain, how to read and reset the thermometer, and what action to take if the temperatures are outside the correct range.

Temperature fluctuations can occur for the following reasons:

- **Restocking the fridge or after a busy immunisation session where the fridge door has been opened frequently**
  Slight rises can occur but should go back to within the normal range after a short while. Once re-stocking is complete, or at the end of the session, read and record the maximum, minimum and current temperatures and complete the comments section on the temperature log. Do not forget to **reset the thermometer** after the reading has been taken. Re-check the temperature after 1 hour to ensure the current temperature has returned to within range and **reset the thermometer**.

- **Fridge malfunction or power failure**

Advice should be sought when:

- The thermometer is reading a current temperature above 8\(^\circ\)C which has not corrected within an hour.

- The thermometer is reading a maximum temperature above 8\(^\circ\)C when the fridge has not been opened.

- Any temperature reading below 2\(^\circ\)C

- A temperature reading greater then 8\(^\circ\)C at the end or start of a day.
If the temperature rises above 8ºC or falls below 2ºC, ascertain if possible how long the temperature has been outside the range and seek advice on whether the vaccines can still be used. Refer to contacts on page 10.

The vaccines from this fridge must not be utilised until advice has been sought. The vaccines can be transferred to a working fridge but should be labelled not for use.

The reason for the fridge malfunction needs checking. It may be possible to bring the temperature back within range by making a small adjustment to the temperature control. Contact an engineer if the fridge appears to be faulty. The fridge should be monitored to check it is operating correctly before any vaccines are returned to it.

Defrost the refrigerator regularly, suggested every 6 to 8 weeks, if it is not self-defrosting. Transfer the vaccines to another refrigerator or a cool box with pre-cooled cool packs whilst defrosting takes place and continue to monitor the temperature to maintain the cold chain. Replace vaccine back in the fridge when temperature is restored. Dates of defrosting should be recorded on the temperature record by writing ‘defrosted’ next to the signature box.

10. Stock Organisation

Keep all vaccines in their original packaging during storage as this is printed with the expiry dates and batch numbers and protects the vaccine from light and damage. It also contains a patient information leaflet or a summary of product characteristics which contains important information.

Vaccines have fairly short expiry dates, so do not over-order or stockpile. Rotate stock so that those with the shortest expiry date are used first. Make regular checks to remove expired vaccines.

To minimise the length of time the fridge door is kept open looking for vaccines, designate certain shelves for different vaccines and keep a list on the outside of the fridge.

ALWAYS check the fridge temperature chart and the vaccine expiry date before administration.

11. Maintenance of the Cold Chain during Clinic Sessions and Domiciliary Visits
Vaccines kept for prolonged periods at high temperatures are rendered ineffective and can also 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 high temperatures are as bad as one long one.

Vaccines should never be left out of the fridge; they should be removed from the fridge just before use. If a busy session is anticipated, then vaccines can be transferred to a cool box to prevent frequent opening of the fridge door. Only take out the required number of doses for one session at a time.

Mark any unused vaccines that have NOT been removed from the validated cool box, “Use First” and date, before returning them to the fridge. This must be done at the end of a session and use them first at the next session. If a marked vaccine is still unused at the next immunisation session it should be discarded (see returns section).

Any vaccines which have been removed from the refrigerator or cool box during the session and not used should be discarded by placing in the appropriate medicinal waste bin.

Nurses transporting vaccines for use in patient's homes, e.g. influenza vaccine, should ensure that the vaccines are out of the refrigerator for as short a time as possible. The vaccine should be carried in a validated cool box to help to keep it cool. Only take the required number of doses out at any time.

Any vaccine that has been taken out on a domiciliary visit must be disposed of if not used, unless maintenance of the cold chain can be proven.

12. **Maintenance of the Cold Chain during School Immunisation Sessions**

A validated cool pack/box must be used when transporting vaccines. Cool boxes must be packed and used in accordance with their manufacturer’s guidelines. E.g. for Vaccine Porters, fill the air space around the vaccine with cool sachets at fridge temperature: replace lid and cool sachets immediately after removing any vaccines from the box.

Cool boxes with frozen ice packs should not be used unless they are designed to prevent the ice pack from touching the vaccines.
The current cool box and cool packs used for the school immunisation sessions should keep vaccines between 2 and 8º C for up to seven hours as long as the lid is kept in place. Steps should be taken to keep the vaccines as cool as possible for the duration of the session i.e. keep the lid in place as much as possible, keep away from sun or heat sources. The cool boxes currently used by the School Nursing Teams are validated to maintain the Cold Chain for a full day session as long as they are used as follows:

- A proportion of the vaccine must be in cool boxes which are not opened until the afternoon.
- Any vaccines remaining in boxes opened in the morning must be used first in the afternoon.

Unused vaccines from boxes which are kept closed until the afternoon may be returned to the fridge at the end of the session. See returns.

13. Returns

Any unused vaccine that has maintained the cold chain should be returned to the fridge as soon as possible after the session. Each box must be marked “use first” and marked with the date it was returned to stock. Any vaccines that have been marked “use first” must be used before any ‘new’ vaccine, and can only be returned to stock on one occasion. In all instances stock marked “use first” MUST be used within 28 days of the date returned to stock.

14. Disposal

All needles, syringes and any empty ampoules, vials, or contaminated waste must be disposed of immediately and the pharmaceutical waste container clearly labelled in line with the LCP Waste Management Guidelines.

Any reconstituted vaccine, open vials or ampoules, or any vaccine left over in multidose vials must be disposed of at the end of each session.

Expired vaccines or those for which the cold chain has not been maintained must also be disposed of.

Containers for all the above waste will be consigned for incineration according to current LCP Waste Management Guidelines.
15. Contact Points for Advice and Further Information

Refer to the index of manufacturers at the back of the British National Formulary (BNF) for contact details for individual vaccine manufacturers.

LCP Medicines Management Team – 01924 351525

16. Equality Impact Assessment

All public bodies have a statutory duty under the Race Relation (Amendment) Act 2000 to “set out arrangements to assess and consult on how their policies and functions impact on race equality.” This obligation has been increased to include equality and human rights with regard to disability, age and gender. The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

In order to meet these requirements, a single equality impact assessment is used to assess all its policies/guidelines and practices. This policy was found to be compliant with this philosophy (see appendix B).

17. Training Needs Analysis

In order to ensure that policies, guidelines and protocols are introduced and work effectively, there is a need to provide adequate training and instruction. As a result, the author(s) of this document have carried out a training needs analysis which has identified the staff who require training, the methodology of training delivery and the frequency that the training will be provided. The policy author must ensure that the details of this training are passed to the Education and Training Department and where necessary, this will then be included in the LCP Training Prospectus.
18. References


*UK Guidance on Best Practice in Vaccine Administration*. The Vaccine Task Administration Task Force, Shire Hall Communications 2001.

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**Appendix A**

**Key Stakeholders Consulted/Involved in the Development of the Policy**

<table>
<thead>
<tr>
<th>Stakeholders Name and Designation</th>
<th>Key Participant Yes/No</th>
<th>Feedback requested Yes/No</th>
<th>Feedback accepted Yes/No</th>
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<tr>
<td>Lucianne Ricketts – Head of Medicines Management</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Medicines Management Team</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Catherine Smyth – Professional/Development Lead</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gwen Riddlesdin – Head of Integrated Governance and Quality</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Jane O'Donnell – Deputy Director of Infection Control, NHS Kirklees</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Sheena Kelly – Senior Infection Prevention and Control Advisor</td>
<td>Yes</td>
<td>Yes</td>
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## Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>Insert Name of Policy / Procedure</th>
<th>Guidelines on the Storage and Handling of Vaccines &amp; Other Medicines Requiring Cold Storage – The Cold Chain</th>
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<tr>
<td></td>
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<tr>
<td>1. Does the policy/guidance affect one group less or more favourably than another on the basis of:</td>
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<td>• Race</td>
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<tr>
<td>• Ethnic origins (including gypsies and travellers)</td>
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<td>• Nationality</td>
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<td>• Gender</td>
<td>No</td>
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<td>• Culture</td>
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<td>• Religion or belief</td>
<td>No</td>
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<td>• Sexual orientation including lesbian, gay and bisexual people</td>
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<td>• Age</td>
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<tr>
<td>• Disability - learning disabilities, physical disability, sensory impairment and mental health problems</td>
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<tr>
<td>2. Is there any evidence that some groups are affected differently?</td>
<td>No</td>
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<td>3. If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?</td>
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<td>4. Is the impact of the policy/guidance likely to be negative?</td>
<td>No</td>
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<tr>
<td>5. If so can the impact be avoided?</td>
<td>NA</td>
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<tr>
<td>6. What alternatives are there to achieving the policy/guidance without the impact?</td>
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<tr>
<td>7. Can we reduce the impact by taking different action?</td>
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Please use a new sheet for each month

Base: .............................................

Month: ...........................................

**Fridge Temperature Recording Sheet**

Name and contact details of designated person responsible for vaccines:

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Current °C</th>
<th>Maximum °C</th>
<th>Minimum °C</th>
<th>Thermometer Reset (Tick)</th>
<th>Signature</th>
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Fax completed forms for the attention of Karen Fisher on 01924 475212

**Please retain a copy for your records.**

If the temperature goes below 2°C or above 8°C, contact the Medicines Management Team on 01924 351525 or contact the vaccine manufacturer directly - see index of manufacturers at the back of the BNF

Person Responsible for Monitoring Vaccines: .................................................................

Deputy: .................................................................

Appendix B
Appendix D

VACCINE STORAGE GUIDELINES

Laminate and place on front of vaccine fridge

- Vaccine storage temperatures must be in the range 2°C to 8°C

- Check and record refrigerator temperatures each working day and before an immunisation session. Suitable recording sheets are provided for you to copy. ‘Probe’ thermometers should be sited in the centre of the fridge, amongst the vaccines and not near the door or ice box. **DO NOT FORGET TO RESET THE THERMOMETER AFTER EACH READING ensuring the CURRENT temperature is in the range 2°C to 8°C**

- If outside this range, quarantine the stock, report immediately to the person responsible for the vaccine cold chain within the practice and seek advice from the LCP Medicines Management Team.

- Refrigerate vaccine deliveries immediately. (This is the responsibility of the member of staff accepting delivery). Vaccines should be stored in original manufacturers packaging.

- Fridges must be kept locked and the keys stored securely.

- The fridge should ideally be wired into a spur plug. Otherwise mark the electrical socket with a cautionary notice advising staff not to switch off power.

- Do not store foodstuffs or specimens in the vaccine fridge at any time.

- Store vaccines in the middle of the fridge, away from cooling elements and freezer compartments. Do not overfill fridge (HPA recommends no more than half full) Do not store vaccines in the fridge door or bottom of the fridge.

- Check expiry dates and rotate stock to ensure shortest shelf life is used first. Always check “Expiry Date” of vaccine following removal from the refrigerator and before administering. Do not keep excess stocks.

- Clean and defrost vaccine fridges on a regular basis. Place vaccines in another fridge or in a validated cool box while this takes place and until the refrigerator temperature is restored to 2°C - 8°C. Mark the date of defrosting on the temperature recording sheet

- Vaccines must be transported to immunisation sessions in validated cool boxes. Ideally vaccines for use at patients’ homes should also be taken in a validated cool box. Only remove the minimum quantity of vaccines required from fridge

- Before any temperature maintained surplus vaccine is returned to the fridge it should be marked and used first for the next subsequent session. This MUST be within 28 days of return to stock.

- Further advice can be obtained from the Medicines Management Team on 01924 351525 or from the vaccine manufacturer (see index of manufacturers at the back of the BNF for contact details).

Person Responsible for Monitoring Vaccines:.................................................................

Deputy: ..............................................................................................................