A Policy for the Storage and Handling of Vaccines and Other Medicines requiring Cold Storage- “the cold chain”

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<tr>
<td>Author(s) name</td>
<td>Nick Beavon</td>
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<td>Nicola Bamford</td>
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<tr>
<td>Author(s) job title</td>
<td>Chief Pharmacist</td>
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<td></td>
<td>Practice Nurse</td>
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<td></td>
<td>Development Lead</td>
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<tr>
<td>Responsible Person</td>
<td>Nick Beavon</td>
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POLICY STATEMENT

GP Practices in Wandsworth will endeavor 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 that handle or administer vaccines within Wandsworth GP Practices. 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 all other policies, procedures and guidance relevant to medicines.

3. Aims and Objectives

The aim of this document is to provide guidance to all staff that 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 Wandsworth GP Practice employees; clinical and non-clinical involved in immunisation and vaccination handling or administration.

It MUST also be followed by all staff that may work for the practice, including those on temporary or honorary contracts, agency staff and students.

Breaches of this policy may lead to disciplinary action being taken against the individual.
5. Accountabilities and Responsibilities

All staff involved with immunisations and vaccinations, or in the storage of other medicines requiring cold storage, must familiarize themselves with the correct procedures contained within 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 2ºC and 8ºC.

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 the patient.

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 manufacturers recommendations regarding storage at all times. **Vaccines should be stored in the original packaging at +2ºC to + 8ºC and protected from light.**

Within the practice, 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 2ºC to 8ºC. Their names should be clearly displayed on the refrigerator door.

Any other staff that may be involved with vaccines must also be trained appropriately.
Reception staff who receive 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 in order that they can be refrigerated immediately on receipt and not left at room temperature.

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 manufacturers 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 must be plugged into sockets labelled or connected in such a way that the electricity supply cannot be accidentally interrupted. The sockets should be marked to avoid them being switched off accidentally. This can be done by placing tape over the plug and labelling 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.
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. For maximum/minimum thermometers, which use a probe, this should be positioned in the centre of the fridge, among vaccines, not near the icebox or the door seal. Integral fridge thermometers are preferable (DH 2006).

The named person or are 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.

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

The temperature recording sheet must be completed each working day and then removed at the end of each month for safe storage in the fridge monitoring record box.

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 immunization session where the fridge door has been opened frequently**

Slight rises can occur but should go back to normal range after a short while. Once restocking is complete, or within one hour, 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.

**Fridge malfunction or power failure** (please ensure plugs are protected and labelled from accidental unplugging or being switched off by cleaners or other staff as vaccines are expensive and this is common cause of vaccines needing to be destroyed as is freezing of vaccines)

Advice should be sought when from the manufacturer of the vaccine or the pharmacy team where:

- **The thermometer is reading a current temperature above 8°C which has not corrected within an hour.**

- **Any temperature reading below 2°C**

- **A temperature reading greater then 8°C at the end or start of a day.**

If the temperature rises above 8°C or falls below 2°C, ascertain if possible how long the temperature has been outside the range and seek advice on whether the vaccines can still be used. Contact individual manufacturers for advice and ensure manufacturers responses are documented.

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 (quarantined) 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.

In the event of a refrigerator failing or breaking down, back-up facilities should be in place. The person in charge transfer vaccines to an alternative fridge within the practice. In the event of this leading to overfilling, staff should discuss with a ‘buddy’ practice or the vaccine suppliers to see if they can offer temporarily storage.

Defrost the refrigerator regularly (in accordance with the manufacturers recommendations), suggested every 6 to 8 weeks, **if it is not self-defrosting.**

Transfer the vaccines to another refrigerator or a approved 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 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
Vaccines stocks should be monitored by a designated person within the Nursing Team to avoid over-ordering or stockpiling.

Surgeries should have no more than two to four weeks’ supply of vaccines at any time.

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 (monthly) 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.

**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 an approved 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 that 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 an approved cool box to help to keep it cool. Only take 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. 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.

13. Disposal

All needles, syringes and any empty ampoules, vials, or contaminated waste must be disposed of immediately following current practice guidelines on the safe disposal of pharmaceutical waste.

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.

14. Contact Points for Advice and Further Information

Refer to the index of manufacturers at the back of the BNF for contact details for individual vaccine manufacturers.

Other contact details are:
Wandsworth Pharmacy Team 0208 871 5151 or 0208 871 5141
Medicines Information Services: Guy’s Hospital 020 7188 8750/3849

15. Training Needs

In order to ensure that policies, guidelines and protocols are introduced and work effectively, there is a need to provide adequate training and instruction. Individuals involved with immunizations and vaccinations, or in the storage of other medicines requiring cold storage, must familiarize themselves with this document and identify their learning needs to those in charge of them.

16. References


https://www.cas.dh.gov.uk/Home.aspx

Please note: From 1 June 2012 all enquiries related to alerts (Rapid Response Reports, Patient Safety Alerts, Safer Practice Notices etc) should be directed to the Central Alerting System Helpdesk: safetyalerts@dh.gsi.gov.uk.

Acknowledgement: Jo Flint, GP Practice Nurse who assisted in producing this policy
Appendices – Fridge temperature monitoring record sheet
Temperature should be between +2°C and +8°C. If the temperatures are outside the recommended range take appropriate action as indicated in written procedure.

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