**Policy for Maintaining the Vaccine Cold Chain (Primary Care)**

**This document describes general principles which are applicable to established vaccines.**

**It does not necessarily apply to COVID-19 vaccines, for guidance on handling these vaccines see** [**https://www.sps.nhs.uk/home/covid-19-vaccines/**](https://www.sps.nhs.uk/home/covid-19-vaccines/)

**NHS Specialist Pharmacy Service**

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**Policy for Maintaining the Vaccine Cold Chain (Primary Care)**

1. **Introduction**

Vaccines may lose their effectiveness if they become too hot or too cold at any time. Vaccines naturally biodegrade over time and storage outside of the recommended temperature range – including during transport – may speed up loss of potency, which cannot be reversed. This may result in the failure of the vaccine to create the desired immune response and consequently provide poor protection. Inappropriate storage and transport may result in wastage and unnecessary costs to the NHS.

1. **Aim**

The principal aim of the cold chain is to ensure vaccines are maintained within a specified temperature range. This policy is designed to give clarity and guidance to staff involved in monitoring and maintaining the cold chain within Primary Care. It aims to reduce the risk of compromising the quality, efficiency and safety of the vaccine programme by ensuring the cold chain is maintained so improving the service for individuals.

1. **Scope**

This policy supports primary care settings in delivering immunisation and vaccination. It sets out the expectations for staff involved in immunisation. It covers ordering, receipt, storage, maintenance of the cold chain, auditing, monitoring stock and incident reporting. This document describes general principles which are applicable to established vaccines. It does not necessarily apply to COVID-19 vaccines, for guidance on handling these vaccines see <https://www.sps.nhs.uk/home/covid-19-vaccines/>

1. **Definitions of terms**

**Cold Chain:** “Cold chain” refers to the process used to maintain optimal cold temperature conditions during the transport, storage, and handling of certain pharmaceuticals, starting at the manufacturer and ending with the administration of the vaccine to the patient.

**Vaccines:** Vaccines are sensitive biological products which may become less effective, or even destroyed, when exposed to temperatures outside the recommended range specified by the manufacturer and/or exposed to direct sunlight or fluorescent light.

**Fridge Item**: Any medicine requiring storage between +2°C and +8°C, including vaccines.

1. **Duties**

All staff involved in ordering, stock control, storage, distribution, transport, monitoring, prescribing, administering, dispensing and disposal of vaccines must follow this policy.

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.

1. **Ordering vaccines**

Vaccine stocks should be monitored regularly to avoid shortages, under or over-ordering or stockpiling

Best practice is to order small quantities on a regular, scheduled basis. Ordering should be undertaken in sufficient time to ensure that there is always an adequate supply for planned clinics and scheduled appointments (e.g. travel vaccines or booster doses).

1. **Receipt of vaccines**

A designated person (or deputy) should be responsible for receipt of vaccines. Reception staff must be aware of the importance of ensuring vaccines are handed over to the person responsible for them as soon as possible and must know what action to take if either the person or their deputy is unavailable.

Vaccines should be checked for damage before signing for them.

If the person receiving the vaccine delivery is not assured that the cold chain has been maintained, they should refuse to accept the order and return it to the supplier.

Vaccines should be refrigerated immediately on receipt and not left at room temperature. Vaccine names, batch numbers and expiry dates should be checked against what is recorded on the delivery note. The member of staff accepting delivery must date and time the delivery note to show when stock was received.

If details of batch number and expiry date are not listed on the delivery note then staff must handwrite these details onto delivery note. Delivery notes should then be stored according to the national guidelines on retaining documentation.

1. **Storage of vaccines**
	1. **Refrigerators**

Specialist 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 never 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. The fridge temperature gauge should be clearly visible to read without needing to open the fridge door. As a minimum for providing adequate refrigerator conditions, the named individuals should ensure that:

* all fridges have a unique identifier, such as a serial number the refrigerator is safe, for example by undertaking regular visual inspections and portable appliance testing (PAT). The Electricity at Work Regulations (1989) require electrical systems to be ‘maintained’.
* the refrigerator is lockable or within a locked room. All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions.
* the refrigerator is the right size to meet the vaccination storage needs, i.e. there is sufficient space around the vaccine packages for air to circulate and there is sufficient capacity for vaccines for seasonal/ additional programmes such as the annual influenza vaccination campaign
* the refrigerator is placed in a suitable position (ventilated and away from heat sources)
* the refrigerator is maintained in a clean condition
* ice is not building up in the fridge. If defrosting is necessary, vaccines should be stored temporarily in a suitable alternative refrigerator or in a validated medical-grade cool box, but for the minimum possible time
* there is a maintenance contract that allows for at least yearly servicing and calibration of the temperature gauge
* steps have been taken to reduce the probability of accidental interruption of electricity supply, such as installing a switchless socket or clearly labelling the vaccine refrigerator plug.

Records should be kept of regular servicing, defrosting and cleaning, calibration and electrical testing. All maintenance actions should be recorded on a log sheet.

* 1. **Thermometers**
* All fridges should ideally have two thermometers, one of which is a max/min thermometer independent of mains power
* If only one thermometer is used, then a monthly check should be considered to confirm that the calibration is accurate.
* Care should be taken that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range.
	1. **Organisation of stock within refrigerator**

Best practice must ensure that:

* The fridge is not overstocked (NB fridge should not be stocked more than 50% full).
* Nothing must touch the back or sides of the fridge (this could result in frozen vaccines)
* Vented boxes or wire baskets can be used to store vaccines within the fridge to help keep vaccine brands together and prevent any loose vaccines falling to the back of the fridge. If vented boxes/wire baskets are used then they should be loosely packed within the box/basket to allow for ample air circulation around the vaccines/prevent crushing damage.
* Certain shelves can be designated for different vaccines – this should be listed on the outside of the fridge to minimise the length of time the door is kept open when searching for a vaccine.
* Vaccines should be removed from all delivery packaging and stored as individual units (in the manufacturer’s original packaging) and not kept in cardboard boxes or plastic bags.
* Stock should be properly rotated by the designated person (i.e. stock with the longest expiry date is put at the back so the stock with the shortest expiry date is always used first).
* Vaccines should be stored in the manufacturer’s original packaging – many are sensitive to light and thus will deteriorate if taken out of boxes.
* Any short dated stock should be clearly labelled and used first.
* Any out-of-date stock should be clearly labelled, removed from the refrigerator immediately and disposed of accordingly to local policies.
* Damaged vaccines – Where the vial or syringe containing the vaccine, diluent or the immunoglobulin is damaged or not intact, the vaccine should not be used. These should be removed from use immediately, labelled as damaged and either disposed of accordingly to the local policy or reported as a product defect.
	1. **Monitoring refrigerators**

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.

The monitoring of fridges is often referred to as observing the four Rs

* ***Read*** - at the same time every day during the working week and signs the sheet
* ***Record*** - in a standard fashion and on a standard form
* ***Reset*** - resets the thermometer after each reading.
* ***React*** - if the temperature falls outside +2oC to +8oC
	1. **Stock control**

The nominated persons are responsible for ensuring there is good stock management and monitoring of stock. The system should:

* keep track of orders
* keep track of expiry dates, and
* keep a running total of vaccines, including wastage

The systems should be updated immediately upon ordering and receipt of vaccines and at the end of clinical sessions where vaccines have been administered.

* 1. **Storage of reconstituted vaccines**

For some vaccines, there is a need to reconstitute the vaccine using a diluent. Storage requirements for the reconstituted vaccines vary and the SPC or packaging insert should be consulted to identify the specific requirements for these vaccines. Generally, it is not good practice to reconstitute vaccines in advance, although in some cases, such as using multi-dose vials, it can be considered. If a vaccine is reconstituted but not used immediately, it is good practice to label the vaccine with date and time of reconstitution and the initials of the person reconstituting the vaccine. These reconstituted vaccines should be stored in line with the guidance given in the SPC or packaging insert and any local policies.

* 1. **Disruption of the cold chain**

In the event of cold chain failure, the following should be undertaken:

* 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 it can be confirmed whether or not they can be used. Make sure they are labelled accordingly.
* Make a list of all the vaccines affected and isolate stock within the refrigerator so it cannot be inadvertently used. **Do not use any vaccine that has been out of the cold chain until advice has been sought from the manufacturer or local Medicines Information Department/CCG Pharmacy team (insert local contact details XXX).**
* Check the plug. Ensure it has not 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.
* Complete the stock incident form on ImmForm
1. **Spillages and breakages**

Spillages on skin should be washed with soap and water. If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought.

COSHH safety data sheets supplied with the product must be referred to when clearing up spillages and breakages Spillages must be cleared up quickly and gloves should be worn. Spillage kits should be used. The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles. The area should be cleaned according to the local chemical disinfection policy or COSHH safety data sheets. Gloves, towels, etc. should be disposed of according to local waste policy.

1. **Transporting vaccines**
* Domestic cool boxes **must not** be used to store, distribute or transport vaccines.
* Validated cool boxes and cool packs from a recognised medical supply company should be used in conjunction with validated maximum–minimum thermometers. A data logger is required if vaccine is to be transported and then subsequently returned to the base refrigerator.
* Cool packs should be stored in accordance with the manufacturer’s instructions, usually at +2˚C to +8˚C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature.
* In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit. The exception to this is when the cool box manufacturer’s instructions specifically state that ice packs should be used.
* Individual manufacturer’s instructions must be strictly adhered to.
* A validated cool box provides ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport.
* With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods, so monitoring is always required.
* The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours.
* Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box with cool packs as per the manufacturer’s instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage.
* When transporting vaccines, named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the vaccine refrigerator. These should be placed quickly into the validated cool boxes and opening must be kept to a minimum.
* An example vaccine in cool box temperature monitoring sheet is available in Appendix 2
	1. **Returned vaccines** **that have been transported**

Vaccination sessions away from the base clinic should be planned in such a way that the correct amount of vaccine is transported, thereby minimising any need to return vaccine. In general, unused vaccines may be returned to the base clinic vaccine refrigerator, providing there is evidence from the data logger that the cold chain has been maintained. Returned vaccines should be marked, segregated and used at the earliest opportunity. This general information is not applicable to all situations and vaccine specific information should be followed where this is available, for example vaccines that are particularly temperature sensitive or require complex handling.

If the cold chain cannot be guaranteed, then advice must be sought from the manufacturer or local Medicines Information Department/CCG Pharmacy team (insert local contact details XXX) and if necessary, the vaccines should be destroyed.

1. **Disposal of vaccines**

All reconstituted vaccines and opened single and multi-dose vials must be used within the period recommended by the manufacturer.

Intact and unopened fridge items which are no longer required (e.g. out-of-date stock) must be disposed of as per the local Waste Policy.

At the end of an immunisation session any remaining reconstituted vaccine must be disposed of in an appropriate coloured sharps bin for incineration. (Use yellow-lidded sharps bin for all vaccines, except for BCG vaccine which must be disposed of in a purple-lidded sharps bin as it is classed as cytotoxic/cytostatic). Refer to the local Waste Policy.

1. **Incidents**

All deviations from this policy or the cold chain must be reported to a designated manager. The incident must be reported according to the local incident reporting policy.

1. **Training requirements**

Any person involved in the maintenance of the cold chain must be suitably trained. Cold chain compliance must be incorporated into immunisation and vaccination training.

1. **References**

Immunisation against infectious disease. Chapter 3 Storage, distribution and disposal of vaccines

PHE Protocol for ordering, storing and handling vaccines 2014

**Appendix 1 Example of Refrigerator Temperature Record Chart**

|  |  |  |
| --- | --- | --- |
| Month | Year | Location |
| Designated staff | Reserve staff |
| Fridge cleaned by | Date cleaned |

PLEASE COMPLETE THE CHART BELOW: RECORDING THE TEMPERATURE SHOULD BE PERFORMED DAILY AT THE SAME TIME PREFERABLY IN THE MORNING BEFORE THE FRIDGE IS OPENED.

The temperature must be between **2- 8°C.** Please record actual, maximum and minimum temperature daily. Reset every time the temperature is taken. If the temperature is outside of these limits reset the thermometer and record the temperature again 2 hours later. Take action if it is still outside of these limits

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **DATE** | **CURRENT** | **MAXIMUM** | **MINIMUM** | **TIME READING TAKEN** | **RESET THERMOMETER** | **INITIALS** | **Action taken for reading outside range of 2-8ºC** |
|  | **BETWEEN****2° - 8°C** | **NOT ABOVE 8°C** | **NOT BELOW 2°C** |  | YES/NO |  |  |
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**Appendix 2: Example Vaccine in Cool Box Temperature Monitoring Sheet**

Vaccines must be stored between **2- 8°C.**

Temperature readings must be taken:

* On arrival to the immunisation site
* Every 2 hourly while at the immunisation site
* On returning to the clinic - before unused vaccines are either returned to the fridge or discarded.

**Date…………………………………… Site…………………………………………………**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Cool bag number** | **Time** | **Current oC** | **Min oC** | **Max oC** | **Re-set****initials** | **Comments and actions taken** | **Initials** |
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