

**Primary Care Services**

**Cold Chain Policy  
 Version 1.0**

Version	1.0
Approved By (sponsor group)	Clinical and Non-Clinical Policy Groups
Ratified By	Quality Assurance Group
Date Ratified	14.0.21
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Implementation Date	Oct 2021
Last Review Date	August 2021
Next Review Date	August 2024

Version Control Summary

Version	Date	Author	Comment
1.0	01.09.21	LD	

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## **1. Introduction**

An effective and credible programme is dependent on the assurance of vaccine potency and quality. “Substandard handling of vaccines may result in a loss of potency or increased reactogenicity in these vaccines. Individuals immunised with these vaccines may be at greater risk of illness or death from the diseases that the vaccines are intended to prevent.” PHE (2012).

The Cold Chain Policy must be adhered to. This will ensure vaccine potency is maintained.

## **2. Policy statement**

All staff must adhere to the cold chain policy to ensure vaccines remain viable.

## **3. Scope:**

This Policy applies to all staff (including those managed by a third party e.g. agency staff or contracted domestic staff).

## **4. Aim:**

This policy sets out the vaccine storage and cold chain procedures in ELFT Primary Care Practices.

## **5. Monitoring Compliance to this policy**

All cold chain incidents will be reported through the screening and immunisations team and on Datix.

## **6. Cold Chain Lead**

Each Practice must have a nominated Cold Chain Lead, supported by the Practice Manager.

In addition to the Cold Chain Lead there should be a named individual with day to day responsibility for fridges in designated areas.

## **7. Ordering, Storing and Handling Vaccines**

The ordering, storing and handling of vaccines should be in line with national recommendations as set out in PHE protocol and detailed within the Immunisation of Infectious Diseases (green book):

PHE: [Protocol for ordering storing and handling vaccines March 2014.pdf](#)

Green Book: <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>

## **8. Taking Delivery**

The nominated cold chain lead should be responsible for receiving vaccines. When vaccines are delivered, nominated staff should certify that there is no damage to the vaccine packaging or any potential leakage of

vaccines. This must be done before signing for the delivery. Once the vaccines have been signed for, 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
- Running total of vaccines, including wastage
- Signature of person receiving delivery

Ensure there is one stock control book for each vaccine fridge. Promptly transfer the stock of vaccines into the fridge, maintaining the cold chain at all times. Vaccines must be kept within their original packaging when placed into the fridges to prevent damage to the vaccine. Keep vaccines away from the sides of the fridge or the floor to allow for air circulation and to avoid them freezing.

## **9. Fridge Maintenance**

Each fridge should:

- have a unique identifier – e.g. serial number
- be lockable or in a lockable room
- be kept in a well ventilated area away from heat sources
- be serviced and calibrated annually
- have associated records for regular servicing, defrosting, cleaning, calibration and electrical testing
- have a switchless socket to reduce the possibility of accidental disruption to the power supply or the plug should be clearly labelled as the vaccine refrigerator plug
- have sufficient space for air to circulate
- not be overstocked
- have regular stock rotation to ensure vaccines are used in date order
- be kept in a clean condition
- not have build-up of ice. If defrosting is necessary vaccines should be moved to another fridge.
- not hold inappropriate items – biological samples and food should not be stored in refrigerators holding medicines

## **10. Temperature Recording**

- Fridge temperature **MUST** be maintained between 2°C to 8°C for a product to remain in licence. A mid-range of 5°C is best practice.
- Fridge temperatures should be recorded once each working day. It should be the first treatment room task for the nurse before the fridge is opened. Temperatures should be recorded on the Fridge Temperature Log (Appendix A example).
- In the absence of a nurse on any given day the nurse should nominate in advance another qualified team member to read and record the temperature.
- Temperature check logs should be kept with each fridge
- Fridge temperature logs are to be signed off each month by the Cold Chain Lead
- A thermometer not linked to the power supply should be used in case of interruption to the power supply
- Thermometers should be reset after each check
- Action should be taken immediately if the temperature reads outside the range 2°C to 8°C
  - Notify the Cold Chain Lead, Practice Manager or Clinical Lead GP
  - When the fridge is opened and out of range due to rotation/restocking/cleaning/auditing record the time and reason on the fridge log sheet, reset after closing the door and recheck in 30 mins to ensure the temperature is back in range.
  - If there is a fridge failure take action according to procedures for Disruption of the Cold Chain (See below)

## 11. Transportation

There may be instances when vaccines need to be transported i.e. for a home visit or to care homes. When transporting vaccines, in order to reduce the possibility of damage during transit, validated cool boxes and cool packs from an appropriate medical supply company should be used. Different types and models of cool boxes have varying storage capacities and sizes of water packs. It is vital to use the correct number and size of water packs, exactly as specified by the manufacturer.

Ensure that validated cool boxes/vaccine carriers are stored as per manufacturer's instructions. Vaccines should be removed from the fridge at the latest possible stage to minimise the length of exposure time out of the fridge and to ensure the cold chain is always maintained. When transporting vaccines ensure they are kept in their original packaging and placed into the cool box/vaccine carrier with the cool packs according to the manufacturer's instructions. It is important to ensure there is no direct contact between the cool packs and the vaccine, as this could cause potential freezing and destabilize the vaccination.

On arrival at the destination, the vaccines should be placed in a vaccine fridge if possible. If not, then the vaccines should always be stored within the cool box/vaccine carrier with the lid closed until required. Similarly, with the vaccine fridge certify that the cool box/vaccine carrier is placed in a secure location until the vaccines are to be administered.

## 12. Disruption of the Cold Chain/Fridge Failure

In the event of a cold chain breach, ensure the following procedures are carried out:

- Do not dispose of any vaccines or storage equipment.
- Ensure that all affected vaccines are quarantined from unaffected vaccines (maintaining the cold chain). Clearly label these as quarantined and 'not for use'.
- Under NO circumstances should these vaccinations be administered to patients until confirmation that they are safe for use.
- Move the affected vaccine stock to an alternative environment (Fridge/validated cool box) that is monitored and able to maintain recommended temperature of +2°C to +8°C. If this is not possible, keep the vaccines in the affected fridge closed until further advice has been sought.
- Ensure the vaccine fridge involved in the cold chain breach, remains switched on at main electrical supply and the thermometer and probe are undisturbed and staff are aware not to access fridge.
- Take an inventory of all exposed vaccines, quantity, batch number/expiry date, and position in fridge. Investigate whether any patients have been vaccinated by stock compromised by the cold chain breach.
- Contact the manufacturers of the affected vaccines to assess which if any vaccines are still appropriate for use 'off label'. For any other vaccines, including travel vaccinations, the manufacturer details are located on the vaccine box and contact details of the relevant company are listed at the back of the BNF. Alternatively, the EMC website can be used to find manufacturer and contact details [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc)
- Discard all vaccinations which have been confirmed as not stable according to National and local policy. Vaccines that include a needle should go in a yellow sharps bin. Vaccines without a needle should go in the pharmaceutical waste bin.
- Contact your local SIT to advise of the incident and confirm the action taken.
- Report the incident on ImmForm [www.immform.dh.gov.uk](http://www.immform.dh.gov.uk) detailing all disposed vaccines and the causes of the incident.
- Report the incident on Datix.

## 13. Waste

- Any vaccine waste to be recorded in the Vaccine Waste Log (Appendix B example).

#### **14. Stock Check and Audit**

- A monthly stock check should be completed on Immform for all centrally procured vaccines.
- The internal practice stock check (example Appendix C) should also be completed every month covering all vaccines.

#### **15. Training**

- All clinical staff and non-clinical staff with any role in receipt, storage or distribution of refrigerated vaccines or medicines should undertake training suited to the fridge used in the practice.
- All immunisers must attend and evidence Basic Immunisation Training and stay up to date via self-learning/e-learning and self-assessment of competencies including formal external update training at least every 2 years as part of statutory and mandatory training requirements.
- Competencies and training will be reviewed for all staff at annual appraisal.

#### **16. Key Contacts**

Screening and immunisation team  
[england.tvatpublichealth@nhs.net](mailto:england.tvatpublichealth@nhs.net)

#### **17. References:**

PHE (2014) Protocol for ordering storing and handling vaccines

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/300304/Protocol\\_for\\_ordering\\_storing\\_and\\_handling\\_vaccines\\_March\\_2014.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering_storing_and_handling_vaccines_March_2014.pdf)

PHE (2012) Vaccine Incident Guidance; actions to take in response to vaccine errors.

<https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>





