Primary Care Services

Cold Chain Policy
Version 1.1

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Approved By (sponsor group)	Clinical and Non-Clinical Policy Groups
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Version Control Summary

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1.1	07.08.24	Julie Roye	Updated to reflect changes and reporting system

Contents

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 putting individuals at risk. Therefore, adherence to the Cold Chain Policy is crucial to ensure vaccine viability.

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 InPhase.

6. Cold Chain Lead

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

Additionally, there should be an individual responsible for the day-to-day management of fridges in designated areas.

7. Ordering, Storing and Handling Vaccines

The ordering, storing, and handling of vaccines should align with national recommendations outlined in the Public Health England (PHE) protocol and the Green Book's chapter on Immunisation of Infectious Diseases.

- PHE Protocol for ordering, storing, and handling vaccines: PHE Protocol
- Green Book: Storage, Distribution, and Disposal of Vaccines - The Green Book Chapter 3

8. Taking Delivery

The nominated Cold Chain Lead is responsible for receiving vaccines. Upon delivery, designated staff must certify the absence of damage or leakage. This should be confirmed before signing for the delivery. The following information must 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 that each vaccine fridge has its own stock control book. Promptly transfer the vaccines into the fridge, maintaining the cold chain at all times. Vaccines must be kept in their original packaging to prevent damage and should not be placed near the sides of the fridge or on the floor to allow for proper air circulation and prevent freezing.

9. Storing Vaccines

Vaccines should be stored in the fridge according to the manufacturer's instructions. It is important to maintain the temperature between 2°C to 8°C for the vaccines to remain effective. Vaccines should be stored in a way that allows easy access and prevents overcrowding. They should not be stored near the

fridge door or in the freezer compartment. Each vaccine should be clearly labelled with the date of receipt and the expiration date.

10. Logging Vaccines on the System

All vaccines received and administered should be logged on the system. This includes recording the vaccine type, batch number, expiration date, and quantity. It is important to keep accurate records of vaccine stock to ensure proper stock management and timely reordering. The Cold Chain Lead or designated staff should be responsible for entering this information into the system.

11. Fridge Maintenance

Each fridge should:

- have a unique identifier – e.g. serial number
- be lockable or situated 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

12. Temperature Recording

It is essential to maintain the temperature of the fridge between 2°C to 8°C for the vaccines to remain in license. The recommended temperature is a mid-range of 5°C. The fridge temperature should be recorded once each working day. This should be the first task for the nurse before opening the fridge. In the absence of a nurse, a qualified team member should be nominated in advance to read and record the temperature. Temperature check logs should be kept with each fridge and signed off monthly by the Cold Chain Lead. A thermometer not linked to the power supply should be used in case of power supply interruption. Thermometers should be reset after each check. If the temperature goes outside the range of 2°C to 8°C, immediate action should be taken, and the Cold Chain Lead, Practice Manager, or Clinical Lead GP should be notified. If the fridge is opened and out of range due to rotation, restocking, cleaning, or auditing, the time and reason should be recorded on the fridge log sheet. The temperature should be rechecked after 30 minutes to ensure it is back in the recommended range.

13. Transportation

When vaccines need to be transported, validated cool boxes and cool packs from an appropriate medical supply company should be used to reduce the possibility of damage during transit. It is important to use the correct number and size of water packs specified by the manufacturer for the cool boxes. Vaccines should be removed from the fridge at the latest possible stage to minimize exposure time out of the fridge. During transportation, vaccines should be kept in their original packaging and placed into the cool box or vaccine carrier with the cool packs as per the manufacturer's instructions. Direct contact between the cool packs and the vaccines should be avoided to prevent potential freezing and destabilization of the vaccination. On arrival at the destination, the vaccines should be placed in a vaccine fridge if possible. If not, they should be stored within the cool box or vaccine carrier with the lid closed until required. The cool box or vaccine carrier should be placed in a secure location until the vaccines are to be administered.

14. Disruption of the Cold Chain/Fridge Failure

In the event of a cold chain breach or fridge failure, the following procedures should be followed:

- Do not dispose of any vaccines or storage equipment.

- Quarantine all affected vaccines, clearly labeling them as "not for use."
- Move the affected vaccine stock to an alternative environment that can maintain the recommended temperature range of +2°C to +8°C. If this is not possible, keep the vaccines in the affected fridge closed until further advice is sought.
- Take an inventory of all exposed vaccines, including quantity, batch number/expiry date, and position in the fridge. Investigate whether any patients have been vaccinated with compromised stock.
- Contact the manufacturers of the affected vaccines to assess which, if any, vaccines are still appropriate for use "off label."
- Discard all vaccinations that are confirmed as not stable according to national and local policy. Vaccines with needles should be disposed of in a yellow sharps bin, while vaccines without needles should be disposed of in the pharmaceutical waste bin.
- Notify the local Screening and Immunisation Team (SIT) of the incident and confirm the actions taken.
- Report the incident on ImmForm, detailing all disposed vaccines and the causes of the incident.
- Report the incident on InPhase.

15. Waste

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

16. 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.

17. 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.

18. Key Contacts

Screening and immunisation team :

- england.tvatpublichealth@nhs.net

19. References:

- PHE (2014) Protocol for ordering, storing, and handling vaccines: PHE Protocol
- PHE (2012) Vaccine Incident Guidance; actions to take in response to vaccine errors: Vaccine Incident Guidance
- Public Health England (2018) Immunisation against infectious diseases (The Green Book) - Chapter 3 Storage, Distribution, and Disposal of Vaccines - The Green Book Chapter 3
- World Health Organization (2015) Temperature sensitivity of vaccines: Temperature sensitivity of vaccines

20. Appendices

Appendix A: Vaccine Fridge Temperature Check Log
Appendix B: Vaccine Waste Log
Appendix C: Monthly Vaccine Stock Check

Appendix A

Vaccine Fridge Temperature Check Log					
Date	**Time**	**Current temp**	**Checked by (signature)**	**Thermometer reset (tick)**	**Comments**

Appendix B

VACCINE WASTE LOG

Surgery:	
Date Log Commenced:	

Please provide details of vaccine waste below:

Date	Reason	Vaccine	Supplier	Batch Number	Quantity	Stock Incident Reported on Immform	Other Action

Appendix C

MONTHLY VACCINE STOCK CHECK

Surgery:	
Fridge Location & ID:	
Date of Check:	
Person Completing Audit:	

Please record stock levels at time of stock check:

Vaccine	Supplier	Batch Number	Quantity	Expiry date	Date Delivered

1. Any issues?
e.g. poor stock rotation; out of date stock found; fridge not clean; fridge over filled

2. Any actions required, by whom and when?
e.g. waste to be reported; order required

Date Actions Complete:
Name: