Primary Care Directorate

LEIGHTON ROAD SURGERY

Vaccine storage and fridge failure

Document Control

Confidentiality Notice

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Contents

Vaccine Storage and Management Policy

Leighton Road Surgery

1. Introduction

Vaccines are critical biological substances that demand precise temperature control to uphold their efficacy and safety. This policy is designed to establish comprehensive guidelines for vaccine management at Leighton Road surgery sites. This includes procedures for vaccine receipt, storage, monitoring, and transport, with the ultimate goal of maintaining the integrity of the cold chain.

2. Scope of Policy

This policy is applicable to all personnel contracted to deliver NHS England services at Leighton Road and Grovebury Road. It should be read in conjunction with the Green Book1, Patient Group Directions (PGDs), and Summary of Product Characteristics (SPCs) provided by manufacturers.

3. Receipt of Vaccine

Upon delivery, designated and trained personnel are responsible for receiving vaccines. Before signing for the delivery, these personnel must inspect for discrepancies, leakage, or damage. Detailed records, including vaccine type, quantity, batch number, expiry date, date and time of receipt, and the receiving person's name, should be maintained. Vaccines must be promptly refrigerated in their original packaging, avoiding exposure to room temperature.

4. Storage of Vaccine

To ensure proper stock rotation, vaccines with the shortest expiry dates should be prioritised. Regular stock checks must be conducted, and expired vaccines should be removed. Vaccines should be stored in locked refrigerators within a secure room, maintaining a temperature range of +2°C to +8°C and protecting them from light. A stock control log should track orders, expiry dates, and running totals of vaccines.

5. Refrigerator

Temperature monitoring should occur twice a day, recording maximum, minimum, and actual readings. Thermometers and data loggers must identify temperature deviations. Even fridges with external electronic displays should have a data logger as a backup. Data should be downloaded and reviewed biweekly. Refrigerators should be positioned away from heat sources, ensuring proper ventilation. Vaccines, as Prescription Only Medicines (POMs), must be stored securely, and the refrigerator should be no more than 50% full for adequate air circulation. Precautions should be taken to prevent electricity supply interruptions, and regular cleaning must adhere to the manufacturer's guidelines.

6. Data Logger and Best Practice

Checking Data Logger

A data logger, placed centrally in the refrigerator, should complement the built-in thermometer. Visual alarms on the data logger are recommended for indicating temperature deviations. Regular downloading and review of data, at least twice a day, help identify and address fluctuations or anomalies, maintaining the cold chain's integrity.

- Set data loggers to 10-minute intervals.
- Check data loggers twice a day.
- Understand data logger functionality.
- Use temperature probes with external displays for triple redundancy.
- Consider the lifespan and calibration of data loggers and temperature probes.

7. Cold Chain Failure

In case of a cold chain failure, follow these steps:

1. Check fridge temperature via data loggers.
2. Transfer vaccines to a working refrigerator or storage box.
3. Do not use vaccines out of the cold chain until advised by the manufacturer.
4. Check the plug and inform designated personnel for repair.

Record failures on Inphase including reasons and actions taken.

8. Transporting Vaccines

Use rigid containers to reduce vaccine damage and maintain temperature during transit. Avoid domestic cool bags; use validated cool boxes and cool packs. Vaccines should be in the original packaging within a cool box, insulated to prevent direct contact, with the container loosely filled to minimise air circulation.

9. Monitoring Arrangements and other considerations

Lead nurse at Leighton Road surgery will review the policy annually or sooner if legislation changes. For detailed information, refer to the Green Book1 and relevant guidelines.

- Ensure correct fridge positioning.
- Make the cold chain policy accessible, with a hard copy in the practice manager's office.
- Report excursions to Screening and Immunisation Team (SIT) immediately.
- Keep service records accessible.
- Consider a secondary cooling device for vaccinations.
- Evaluate the need for fewer fridges, such as a "receiving fridge" and two other fridges.

10. Disruption of the Cold Chain

Immediate action:

1. In the event of a cold chain breach, ensure the following procedures are carried out: Do not dispose of any vaccines or storage equipment.
2. 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.
3. 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 then keep the vaccines in the affected fridge closed until further advice has been sought.
4. Ensure vaccine fridge involved in 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.
5. 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. Complete Vaccine Incident checklist form (Appendix 8).
6. Contact the manufacturers of the affected vaccines to asses which if any vaccines are still appropriate for use ‘off label’. For a list of all manufacturers and their contact details (Appendix 4). Discard all vaccinations which have been confirmed as not stable according to National and local policy.
7. Contact your local screening and immunisation team (SIT) to advise of the incident and confirm the action taken. You will be asked to complete a Significant Event form (Appendix 7). For contact details of your local SIT see Appendix 3.
8. Report the incident on ImmForm www.immform.dh.gov.uk detailing all disposed vaccines and the causes of the incident. NHS England and NHS Improvement 10 The East Screening and Immunisation Team has developed this policy which provides information on what to do in the event of a potential cold chain breach. Pathway 1 (Appendix 5) should be followed in the event of a cold chain breach. Pathway 2 (Appendix 6) should be followed for Investigating serious cold chain breaches. The local SIT should be informed of what happened and a significant event form should be completed.

9. Duty of Candour

Contacting patients if there has been a breach, take advice and guidance before following this step and ensure that this is documented in the patients’ notes.