

Primary Care Directorate

LEIGHTON ROAD SURGERY

Vaccine storage and fridge failure

Document Control

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B. Document Details

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Introduction

Vaccines are biological substances that may lose their effectiveness quickly or become potentially dangerous if they become too hot or too cold at any time, especially during transport and storage.

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of $+2^{\circ}$ C to $+8^{\circ}$ C until the point of administration. Vaccines must not be stored in a domestic fridge. Food and drink must not be stored in vaccine fridges.

All vaccines must be refrigerated and protected from light. They must not be frozen. The efficacy of vaccines depends on their temperature being kept within the range 2-8 degrees C from manufacturer to patient. If storage recommendations are not followed, manufacturers will disclaim responsibility for any subsequent failure of the product. Use of a vaccine that has not been stored correctly is likely to be outside of the licensed use of the vaccine and therefore it cannot be used under a PGD.

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.

Scope of policy

This policy supports immunisation and vaccination programmes across Leighton Road surgery sites at Leighton Road and Grovebury Road. It has been developed to ensure that manufacturers' recommendations are adhered to, to protect individual patient care. It should be read in conjunction with the Green Book1, appropriate Patient Group Directions (PGDs) and Summary of Product Characteristics (SPCs) that are supplied by manufacturers.

This policy applies to all staff contracted to deliver services on behalf of NHS England.

This policy should be used in conjunction with the Directorate Cold Chain Policy



Cold Chain Policy.pdf



Receipt of Vaccine

Trained person(s) should be nominated for receiving vaccines.

On receipt of the delivery the designated person(s) should check against the order for discrepancies and for leakage or damage before signing for them. Distributors or manufacturers will not accept items for return once they have left their control.

The following information should be recorded:

- Vaccine type and brand
- Quantity
- Batch number and expiry date
- Date and time of receipt
- Name of person receiving goods

Vaccines must be kept in original packaging and refrigerated immediately on receipt and must not be left at room temperature.

Storage of Vaccine

Rotate stock so that those with the shortest expiry date are moved to the front of the refrigerator and used first. Make regular stock-checks to remove expired vaccines. Keep vaccines in more than one fridge where this is possible. All vaccination fridges must be kept locked within a locked room.

A stock control log should be kept, to keep track of orders, expiry dates and running totals of vaccines.

Vaccines are to be stored in their original packaging at +2oC to +8oC and protected from light, as exposure to ultraviolet light will cause loss of potency.

Refrigerator

Temperatures in the fridge are to be monitored and recorded once a day and documented as maximum reading, minimum reading and actual reading. The maximum and minimum functions must be reset after each temperature reading.

Thermometers will identify when the temperature may have been outside the recommended range.

Fridges that have an external electronic display still need a data logger in case of failure of the built-in thermometer or loss of power to the refrigerator. These should be downloaded weekly and kept a log off.



Opening of the refrigerator door should be kept to a minimum to maintain a constant temperature.

Refrigerators should not be situated near a radiator or any other heat source and should be appropriately ventilated. Air should be able to circulate freely on all sides of the refrigerator. Failure to do this may result in overheating of the fridge, especially in very hot weather.

All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Either the refrigerator is lockable, or the room is locked when not occupied by a member of staff.

Vaccines must never be left unattended once removed from the refrigerator. Sufficient space is to be provided within the fridge for vaccines to allow for air to circulate freely. The fridge should be no more than 50% full.

Accidental interruption of the electricity supply should be prevented by using a switchless socket or by placing cautionary notices on plugs and sockets. The refrigerator should be cleaned according to manufacturer's guidelines.

Disruption of Cold Chain

In the event of cold chain failure, the following will apply:

- Check the temperature inside the fridge via the data loggers and try to ascertain how long it has been without power.
- Remove all vaccines to another working refrigerator or storage box until you can confirm whether they can be used.
- Do not use any vaccine that has been out of the cold chain until advice has been sought from the manufacturer.
- Check the plug. Ensure it hasn't been disconnected.
- Inform the person designated to oversee all the refrigerators or a manager, in their absence, so that a repair engineer can be called.

If the manufacturer advises that the vaccines can be used, vaccines must be clearly marked and used first. Any stock that needs to be destroyed must be replaced with new stock.

All failures need to be recorded on DATIX with the reasons of the failure and the actions taken.

Transporting Vaccines

Suitable rigid containers will be always used to reduce damage to vaccines during transit and maintain temperature. Domestic cool bags should not be used to store, distribute or transport vaccines. Validated cool boxes (with maximum-minimum thermometers) and cool packs from a recognised medical supply company should be used.



Vaccine to be kept in original packaging and placed into a cool box with cool packs recommended by the manufacturers' instructions. These must be insulated to prevent direct contact with the vaccine. They should be placed in the bag in accordance with manufacturers recommendations. They must not come into direct contact with the vaccine. Space within the container must be loosely filled to minimise circulating air.

Cool boxes and packing material should be stored at the lowest temperature possible prior to packing with the vaccine load and vaccine should be loaded as late as possible before departure to minimise exposure time out of the fridge.

On arrival at the vaccination session, vaccines should be transferred to a refrigerator if available. Otherwise, they must be left in the closed cool box until they are required.

Monitoring Arrangements

The effectiveness of this policy and procedure will be reviewed on an annual basis, and sooner, subject to changes in legislation. The review will be undertaken by the Lead nurse at Leighton Road surgery.



