

Cold Chain Policy

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Background

The efficacy of most vaccines depends on maintaining the cold chain within the range of 2C - 8C. It begins when the vaccine is manufactured and ends with the local immunisation provider at the time of administration. Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage.

Inadequate temperature control during storage and transport of vaccines can result in failure to provide a satisfactory level of immunity as well as vaccine wastage.

This document is intended to give advice to all staff working within Hope Citadel Healthcare on the storage, handling, distribution, and disposal of vaccines.

It must be used in conjunction with the most recent edition of "IMMUNISATION AGAINST INFECTIOUS DISEASE" (HMSO); and individual manufacturers' / suppliers' guidelines.

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

There must be a designated person and deputy in each service area, who should monitor all aspects of vaccine handling.

This document describes the standards pertaining to the ordering, receipt, and storage of vaccines as well as appropriate action to be taken during and after a session. In addition, untoward occurrences are discussed in the section on Incidents.

The coronavirus vaccine comes with additional requirements which may be handled at a PCN level. All guidance from the PCN CD must be followed.

Role of Clinicians

All clinicians are individually responsible for following procedures and practices as identified within the policy in order to maintain the cold chain.

Role fridge monitor

- To monitor and maintain the refrigerator in their community base.
- To ensure that they have received training on the cold chain policy
- To clean the inside of the medicine refrigerator every 6 months.
- The maximum and minimum fridge temperature is logged and reset daily.

Storage

Vaccines must be stored in accordance with manufacturers' guidelines of a safe temperature between 2C - 8C to ensure their efficacy.

Vaccines must be stored in refrigerators which are designated for that purpose only, i.e., a 'pharmacy fridge' or 'vaccine refrigerator', ordinary domestic fridges must not be used.

Refrigerators must be wired directly to a fuse spur to avoid accidental unplugging, or plugs must be taped and labelled 'pharmacy fridge do not unplug'.

Refrigerators must be lockable or within a locked room when not occupied by a member of staff.

Refrigerators must be serviced, defrosted, and cleaned on a regular basis. Records should be kept of any servicing or defrosting. It is strongly recommended that refrigerators used for storing vaccines should have automatic defrost cycles, otherwise defrost monthly.

When defrosting the refrigerator, move the vaccines to a second refrigerator. This temporary storage refrigerator must also be monitored to ensure the correct temperature 2C - 8C is maintained. Alternatively, place the vaccines in a pre-cooled insulated container with ice packs. Continue to monitor the inside of the container until the normal vaccine refrigerator is ready for use again. At this time checks should be made on the expiry dates of the vaccines.

Refrigerators should not be more than 50% full as this prevents circulation of cold air.

Vaccines must not be stored in the door, bottom drawers or next to the freezer plate of refrigerator.

To prevent the internal temperature rising, the refrigerator must not be opened unless necessary.

Vaccines should be kept in original packaging to retain information on batch number and expiry date. The packaging is also part of protection against light/direct sunlight and changes in temperature.

Vaccines **MUST NOT** be frozen and **MUST NOT** be used if they have been frozen.

The fridge should not be sited in front of a radiator or heat source that could affect the working of it. There should be enough space for air to circulate freely around the back of the fridge.

A maximum/minimum thermometer should be used in refrigerators where vaccines are stored, irrespective of whether the refrigerator incorporates a temperature indicator dial. The following should be checked and recorded daily i.e. Monday to Friday (see appendix 1)

- A) The maximum temperature
- B) The minimum temperature
- C) The actual temperature

The designated person is responsible for ensuring that a person has been nominated to check the temperature of each fridge daily and that this duty is transferred to a deputy whenever necessary.

The thermometer should be reset after each reading is made.

Alternative storage facilities must be available and should be used immediately if the refrigerator fails to function.

If the correct temperature has not been maintained, staff should gather information as suggested on the temperature monitoring chart (appendix 1) and report to the Manager. Contact medicines management and / or the local immunisation Co-ordinator

Cool boxes may be used but only as an interim measure. Action must be taken immediately to rectify the fault or obtain another refrigerator.

Patient held vaccines should be discouraged. Exceptionally patients may be asked to transport vaccines and/or immunoglobulin and store them for short periods of time. Should the need arise advice on appropriate storage should be given to the patient.

The refrigerator is not to be used to store anything other than vaccines or drugs.

Ordering

Sufficient quantities of vaccine must be held to meet the largest known routine demand. Best practice is to order smaller quantities on a regular, scheduled basis.

- Do not over order or allow excess stocks to build up.
- Stocks should be ordered on a “topping up” system.
- Each service area should have a protocol for obtaining vaccines for additional or non-routine requirements.
- The Department of Health recommends that a 2–4-week supply of childhood vaccines should be held.

Receipt of Vaccines

Vaccines must be maintained at the correct temperature, throughout the delivery process.

Vaccines will be delivered under refrigerated conditions.

All members of staff (including temp staff) must be aware of the importance of maintaining the cold chain.

The person receiving the vaccines must not accept the delivery if there is any doubt that the cold chain has not been adhered to.

The person receiving the vaccines will sign for them, noting time of despatch/arrival, signs of leakage, damage, or discrepancies before signing for them. Manufacturers will not accept any vaccine for return once it has left their control.

The vaccines must be placed in the refrigerator immediately. If the person receiving the vaccines is non-clinical and not trained to log vaccine deliveries, they should notify a clinician (most appropriately a Nurse or HCA) that the vaccines have arrived and are in the refrigerator.

Vaccines should be date checked and rotated to ensure that the oldest stock is used first.

Batch numbers and expiry dates of all vaccines must be recorded in a book kept near the refrigerator. All vaccines removed must be signed out.

During the Sessions

The effectiveness of vaccines must be maintained at all times.

Vaccines should be removed from the refrigerator just before use. If a busy session is envisaged vaccines may be transferred to a cool box to prevent repeated opening and closing of the fridge door and help maintain the cold chain.

Any dated vaccines (indicating that they have been removed from the fridge in a previous session) must be used first.

A record should be maintained of all vaccines removed from the refrigerator.

A validated cool box should be used to transport vaccines to a subsidiary site. A domestic cool box can only be used if appropriate temperature measuring with maximum and minimum thermometer is used (appendix 2)

Vaccines should be placed in the cool box immediately before leaving the main storage area and the date and time recorded. Ice packs must not be placed in direct contact with the vaccine boxes.

Only the amount required for the session should be taken.

After the Session

Vaccines must remain effective for subsequent use.

Any unused vaccines should be dated before returning them to the refrigerator. These should be used first at the next session. Their return to the fridge must be logged.

Vaccines which have been transported in a cool box or other insulated container with frozen ice packs can only be returned to the refrigerator if they have not been taken out of the cool box and the temperature within the cool box has remained within the range +2 to +8C.

N.B. Vaccines must not be allowed to come into contact with the ice packs as it can cause the vaccine to freeze.

All vaccines returned to the refrigerator should be recorded and clearly labelled.

Any opened or prepared vaccines and those returned from an outside clinic on more than one occasion must be disposed of in an appropriately coloured sharps bin as per Hope Citadel infection control policy for waste disposal.

Disposal

Vaccines must be disposed of safely.

Vaccines must only be disposed of in the appropriately coloured sharps bins for incineration.

Any sharps bin used at subsidiary sites should be returned to the main storage point at the end of the session.

Adverse reactions

Action must be taken promptly if adverse reactions occur.

Serious adverse reactions should be reported to the Medicines Control Agency (MCA) on the appropriate yellow card.

Adverse reactions are extremely rare so if several occur within a short time scale they should be reported to the Consultant in Communicable Disease Control (CCDC) at the Health Protection Unit at Peel House, Tel no: 0161 786 6710.

Hope Citadel CIC will notify the appropriate staff if vaccines need to be recalled.

Audit

It is the responsibility of the Vaccine Controller in each service area to ensure that this advisory document is followed.

Equipment Failure

Equipment failure includes changes in temperature that would lead to the degrading of the vaccine making it unusable this occurs on the temperature raising above + 8C or the temperature dropping below + +2C .

Dispose of all vaccine as per policy.

Identify what the problem is.

Inform the Manager.

Complete an incident/adverse events form.

References and information

'Green book' - Immunisation against Infectious Diseases, HMSO 2006. Available on URL: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

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