



Western Health
and Social Care Trust

COLD CHAIN POLICY

January 2009

Title	Cold Chain Policy
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1. Introduction

The pharmacy departments in Erne, Tyrone County and Altnagelvin hospitals supply vaccines for the childhood immunisation programme in primary care. It is a requirement that suitable arrangements are in place to maintain the cold chain during storage and transportation of these vaccines¹. When the cold chain breaks down, as has happened in the UK recently², the consequences are serious. This can lead to a risk of reduced immunity in the patient population, a need to repeat immunisation, a loss of confidence in the service and wasted resources. This policy aims to aid compliance, by all involved in the handling of vaccines, with the requirements of the cold chain.

Throughout this document the term “vaccine co-ordinator” will be used to refer to the named persons responsible for maintaining the cold chain. Within General Practice this will be a member of staff allocated with this responsibility and it is envisaged that they will work closely with the named health visitor for the particular practice to ensure that the cold chain is maintained. A team approach ensures that good practice standards are met.

Aim

To ensure that vaccines are stored at their optimum recommended temperature from the time of manufacture until administration.

Objectives

- To ensure that all relevant members of the health care team are aware of their responsibilities in relation to the cold chain policy.
- To ensure that staff involved in the policy receive appropriate training.
- To ensure that all equipment is standardised and maintained.
- To ensure that storage conditions meet legal requirements in accordance with the conditions specified in each vaccine’s product licence.

Training

All staff including pharmacy, transport, clerical, nursing and medical staff dealing with vaccines must have appropriate training on the cold chain policy.

Roles and responsibilities

- The pharmacy department will put arrangements in place for the validated cold chain supply of vaccines to Trust-owned health centres, school nurse departments and independent general medical practices according to local arrangements.
- Trust-owned health centres, school nurse departments and independent general medical practices will ensure suitable validated cold storage is available when vaccines are being used or stored.
- Each Trust- owned health centre, school nurse department and independent general medical practice must have one trained individual (vaccine co-ordinator) with at least one trained deputy, responsible for the ordering, receipt and storage of vaccines.
- Trust- owned health centres, school nurse departments and independent general medical practices will be responsible for auditing the storage of vaccines regularly (at least annually).
- Trust- owned health centres, school nurse departments and independent general medical practices will have a suitable vaccine refrigerator (Appendix 1) and will maintain and monitor it as per the guidelines.

2. Day to day management and storage of vaccines

The vaccine co-ordinator from Trust- owned health centres, school nurse departments or independent general medical practices will be responsible for the management and storage of vaccines

Receipt of orders

The vaccine coordinator (named person responsible) must, on receipt of the order:

- Check for discrepancies and obvious signs of damage.
- Check the transport container to make sure the correct cool packs are in place and are still cold.
- Check the vaccine dispatch note to work out how long it has been since the vaccines have been removed from the refrigerator. The note should be completed and returned to the pharmacy.
- Place the stock immediately in the vaccine refrigerator.

Ordering and storing vaccines

Care should be taken not to overstock the vaccine refrigerator as this impedes cold air circulation and prevents the achievement of consistent, stable temperatures especially when large amounts of stock are being held.

Adapted from National Vaccine Storage Guidelines: Strive for Five (Australian Government) ³
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The formula below can be used when ordering vaccines for the practice.

Quantity required (i.e. quantity used in the last period) minus the amount left over from the last period plus 10% of quantity used in the last period (reserve stock).

e.g. 30 DtaP/IPV/Hib (quantity used last period) minus 5 DtaP/IPV/Hib (amount still in the refrigerator) plus 3 DtaP/IPV/Hib (10% of quantity used in the last period).

Therefore the quantity required is 28 DtaP/IPV/Hib.

Monitoring vaccines on a weekly basis to ensure that overstocking does not occur

- Check that the temperature readings are between 2 and 8 degrees Celsius.
- Record the date and time of receiving the vaccine in a logbook.
- Rotate the vaccine stock to ensure that the vaccines with the shortest expiry date are used first.
- Check the expiry dates of the vaccines regularly; expired vaccines should be discarded in a purple-lidded sharps container for incineration

3. Community fridge management guidelines

Pharmaceutical products must be stored in accordance with the conditions specified within their product licence.

Storage conditions for pharmaceutical products are specified in their respective data sheets and potency can only be guaranteed if the products have been maintained at the recommended temperatures.

It is the responsibility of the vaccine co-ordinator to ensure compliance with the following protocol.

3.1 Refrigerators should be of a suitable standard (see Appendix 1) and be sited in an environment where the ambient temperature does not affect the temperature control of the refrigerator, i.e. the external environment should be between 10 and 32 degrees Celsius. The top surface must not be used for storage.

3.2 A least once annually a service / calibration should be carried out by an approved contractor to calibrate the temperature monitoring device and ensure the refrigerator and alarm systems are functioning correctly. In Trust-owned health centres and school nurse departments, the vaccine co-ordinator will arrange this through the hospital estates department for refrigerators owned and maintained by the Trust. For refrigerators owned and maintained by independent general medical practices, a service contract should be set up with a commercial company to do this. This should include provision to have an engineer attend a breakdown within a defined time period. Contact Pharmacy for further information.

3.3 The refrigerator must be kept locked. The door must be closed and locked as soon as stock is removed/ replenished.

3.4 Only pharmaceuticals should be stored in the refrigerator.

3.5 Pharmaceuticals that must be stored between 2 and 8 degrees Celsius must be transferred to the refrigerator immediately on delivery to Trust owned health centres, school nurse departments or independent general medical practices.

3.6 Temperatures must be maintained between 2 and 8 degrees Celsius.

The refrigerator temperature, minimum temperature and maximum temperature should be recorded at least once daily using a digital maximum-minimum thermometer. This may be part of the control panel for the fridge or can be purchased as a stand-alone thermometer. Using a stand-alone thermometer gives additional assurance if there is ever a query with the control panel reading. The thermometer should have an external probe, which must be placed amongst the stock (staff must be trained how to use these thermometers). Temperatures must be recorded in the Pharmaceutical Refrigerator Temperature Log (sample log sheet in Appendix 2).

The refrigerator should be inspected once per week and cleaned if necessary.

The following things should be noted:

- a. Cleanliness
- b. The fridge capacity doesn't exceed 50%.
- c. There is no inappropriate storage of specimens, food or drink.
- d. General condition of the fridge.
- e. Vaccines are not stored in the bottom drawers or door shelves.

Comments in relation to the inspection should be recorded in the Pharmaceutical Refrigerator Temperature Log.

3.7 A fridge alarm will sound when the temperature falls below 2 °C or rises above 8 °C. When deviations are noted and/or when the alarm sounds, appropriate action must be taken **immediately**. Contact pharmacy for advice on what to do with stock.

3.7.1 If the temperature displayed and the minimum temperature are both registering 1°C:

Each vaccine must be inspected individually to ensure the contents have not frozen. If any are frozen, all vaccines must be removed from the defective refrigerator and must be recorded on the “vaccine returns for disposal form” (Appendix 5) stating that vaccines are for disposal due to refrigerator malfunction. Vaccines and returns sheet should be placed in a plastic bag and returned to Pharmacy for disposal. Vaccines that show no signs of freezing should be placed in a prearranged standby refrigerator. The temperature of the standby refrigerator should be monitored as stated in point 3.6 above. Contact pharmacy for advice on whether these vaccines can be used.

3.7.2 If the temperature displayed and / or the minimum temperature are registering 0°C or less:

Vaccines must **not** be used and should be sent to pharmacy for disposal as detailed in section 3.7.1

The Estate Services Department/ Refrigerator Service Contractor should be contacted to request repair of the defective fridge. A standby refrigerator should be identified to store future orders of vaccines

3.7.3 If the temperature is above 8°C

Check if the refrigerator's door has been left open.

The temperature should be monitored and recorded every 10 minutes to ensure it falls within the acceptable range 2-8°C.

3.7.4 If the temperature has not returned to 2-8° C after 30 minutes:

Products must **not** be used.

The Estate Services Department/ Refrigerator Service Contractor should be contacted to request repair of the defective fridge. A standby refrigerator should be identified to store future orders of vaccines.

Products should be removed from the defective refrigerator and sent to pharmacy for safe disposal as outlined in 3.7.1.

3.8 Trust-owned health centres, school nurse departments and independent general medical practices which close at weekends must endeavour to hold minimum stocks when closed. Temperatures **must** be recorded last thing on Friday afternoons and as soon as the practice/ department re-opens. If there is any indication of temperatures having been outside limits the stock must **not** be used and must be returned to the Pharmacy Department as instructed above.

4. Transportation and storage of vaccines (to other centres or prior to administration in a patient's home).

Vaccines are supplied to Trust-owned health centres, school nurse departments and independent general medical practices from Altnagelvin Hospital, the Erne Hospital and Tyrone County Hospital. In the absence of refrigerated transport it is important that steps are taken to ensure the maintenance of the cold chain at all stages.

- A dedicated, validated system must be used for transporting vaccines. A system, utilising polystyrene boxes with cool packs has been validated for vaccine transport under controlled conditions for 3 hours. These will be used for the transportation of vaccines from each hospital pharmacy department.
- Cool packs from the refrigerator in a plastic, commercial cool box will NOT give cold chain conditions for any length of time. Contact Pharmacy QA Dept, Altnagelvin Hospital, WHSCT Ex 3591 for advice on this.
- Ice packs may be used in exceptional circumstances. If this is the case, they must be left at room temp for at least 20 minutes before use and must be wrapped in bubble wrap.
- The container used for transporting vaccines should be packed immediately prior to dispatch unless it can be stored in a validated cold room or refrigerator.
- Vaccines must be kept in their original packages and placed into the transportation container (Appendix 3).
- A vaccine log (see appendix 4) must be completed. The log must be kept in the plastic envelope on the box and completed sheets filed in the practice.

5. Use of vaccines at clinics and disposal of waste.

- The minimum amount of vaccine necessary should be removed from the refrigerator or cool box at any one time.
- Vaccines should be stored under cold chain conditions for the duration of the clinic. Ideally a vaccine refrigerator will be available in the room being used for administration. If a vaccine refrigerator is not available, a dedicated validated system must be used for storing vaccines during the clinic.
- Cool packs from the refrigerator in a plastic, commercial cool box will NOT give cold chain conditions for any length of time. Steps should be taken to ensure cold chain is maintained at all times. Any vaccines that cannot be stored under validated conditions should be used during that vaccination session only and any remaining discarded. Contact Pharmacy QA Dept, Altnagelvin Hospital, WHSCT Ex 3591 for advice on this.
- Vaccines should be reconstituted in accordance with the manufacturer's instructions.
- At the end of the session, opened ampoules and vials should be placed in a purple-lidded sharps container for incineration.
- At the end of the session, unused vaccines which have not been stored in a vaccine refrigerator but have been stored in a validated container should be marked with the date of the session, the length of time they were out of the refrigerator and that they be "used first" for the next vaccination clinic. Only vaccines that have been stored under validated conditions can be treated this way. These must be

returned on the same day to the refrigerator. Such vaccines must not be recycled in this way a second time.

- At the end of the session unused vaccines, for which there is no guarantee that they remained inside 2-8 degrees Celsius, should be disposed of in a purple-lidded sharps container.

Unused vaccines, those which have expired and associated vaccines sharps waste, should be disposed of as hazardous waste under the Hazardous Waste Regulations (NI) 2005. This means placing this material in a purple-lidded sharps box or burn bin and disposing of it by incineration via a suitable waste disposal carrier.

References

¹ Immunisation Against Infectious Disease – “The Green Book” August 2006.

² NHS Grampian (2007) Report of the Investigation into Northfield Vaccination Incident

³ Australian Government Department of Health and Aging. The National Vaccine Storage Guidelines - Strive for Five. Commonwealth of Australia, 2005.

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Appendix 1

Vaccine refrigerator specification

A refrigerator should be of an adequate or appropriate size to allow vaccines to be segregated and arranged to ease selection, access and stock control, as well as allowing an adequate range and stock level to be held to meet patients' needs.

It should be located in a cool, shaded, well-ventilated or air-conditioned room of low through-traffic and where exposure to direct sunlight is prevented. If possible the power supply should be backed-up in the event of a power cut.

The refrigerator should be monitored at least once daily. It should be cleaned at regular intervals as required.

The basic requirements of a refrigerator used to store vaccines are as follows:

1. Must be capable of being locked.
2. A glass door is preferable, as it allows stock be looked at without the need to open the door.
3. Grille type shelving will allow good air circulation.
4. Temperature must be maintained between 2°C and 8°C. There should not be fluctuations greater than $\pm 2^{\circ}$ C within these limits.
5. Cooling should be fan-assisted to aid temperature recovery after door opening.
6. Automatic defrost should take place at appropriate intervals
7. Audio/visual alarm signal on temperature deviation, with remote alarm terminals to mains failure alarm signal if appropriate.
8. Microprocessor digital temperature control with MAX/MIN memory for continuous monitoring
9. A stand-alone maximum minimum thermometer to allow independent temperature measurement.

10. A notice “DO NOT SWITCH REFRIGERATOR OFF” must be affixed to the plug and socket.

Appendix 3 Procedure for packing vaccines into a transport box

1. Place one cool pack into the bottom of the box.
2. Pack the vaccines immediately into the box.
3. If the box is only partly full, use bubble wrap to fill it up.
4. Place the other cool pack on top of the contents
5. Immediately close the box and place it into the outer bag
6. Record the details on the vaccine dispatch form/log (Appendix 4).

