



Chapter 5

Storage and Handling of Vaccines

5.1 Objectives

To gain an understanding of the correct procedures for the handling and storage of vaccines including

- Knowledge of the Cold Chain and its importance to vaccine efficacy
- Knowledge of the HSE National Cold Chain Delivery Service and vaccines available through this service
- Description of the mechanism for ordering, delivery and storage of vaccine including use of designated vaccine refrigerators
- Knowledge of recommended temperature range for vaccine storage
- Understanding how to audit the cold chain within your own practice
- Procedures to be put in place following a disruption to the cold chain e.g. following refrigerator breakdown
- Understanding how to dispose of out of date, unused vaccines etc.

5.2 The Cold Chain and its importance to vaccine efficacy

Vaccines are biological substances that can lose their effectiveness if they become too hot or too cold and may not therefore offer protection against the disease specified and will need to be discarded.

The “Cold Chain” is the system of correct storage, transport and maintenance of vaccines to ensure that they are protected from inappropriate temperatures and light from the time of manufacture to the time of administration. The safe temperature range for storage, transport and maintenance of vaccine is between +2° and +8° Celsius.

Maintaining the Cold Chain is important to

- Ensure that potency and efficacy of the vaccine is maintained
- Ensure benefit from immunisation
- Ensure compliance with Marketing Authorisation

5.2.1 The HSE National Cold Chain Delivery service

All vaccines are stored and delivered under temperature controlled conditions by the HSE National Cold Chain Delivery Service. This service is provided as a partnership between the Health Service Executive and a contracted distribution company. Information about the Cold Chain Delivery Service is available on the National Immunisation Office (NIO) website www.immunisation.ie.

5.2.2 Vaccines available through the National Cold Chain Delivery Service

The vaccines that are available through National Cold Chain Delivery Service are procured by the HSE. Some vaccines such as BCG are only available for supply to HSE health centres and hospitals. Available vaccines may change due to HSE vaccine contracts and changes in the vaccination schedule. Further information on vaccines is available on www.medicines.ie and at www.immunisation.ie.

5.2.3 Vaccine ordering

GPs who hold an immunisation contract can order vaccines on a monthly basis through this service. Vaccines are also provided to Community Health Doctors who run the school immunisation service,

BCG clinics and to hospitals. Vaccines are delivered directly to the GP surgery, HSE health centre or hospital pharmacies.

The quantity of vaccine order can be determined by

- Quantity used since last delivery
- Storage volume within the refrigerator
- Vaccines currently in the refrigerator
- Seasonal variation e.g. influenza vaccine
- Disease outbreaks.

The order form explained

There are two order forms available – one is used by GP practices the other is used by hospitals and health centres (Appendices 4 and 5). The order form contains information on the following.

- **GP/Clinic details:** Account Number/Name/Address /Contact Name and telephone number
- **Contact Details:** National Cold Chain Delivery Service, Customer Services Contact Details
- **Vaccines:** List of Available Vaccines
- **Quantity Details:** Details on the quantity of each vaccine ordered
- **Change of contact details:** This captures any change to contact details or other relevant information
- **Signature and Date:** Name and signature of person requesting the order

The current order forms can be downloaded from the National Immunisation Office website www.immunisation.ie.

5.2.4 Vaccine Delivery to the surgery or HSE health centre

A named, trained and designated person and deputy should be in charge of ordering vaccines and be responsible for receipt and storage of vaccines. A helpful checklist for vaccine storage is found in Appendix 6

- Vaccine deliveries must be checked against the order for any damage or discrepancies which must then be reported to the National Cold Chain Delivery Service
- Vaccines must be immediately placed in the vaccine refrigerator and must not be left at room temperature.

5.3 Vaccine Storage

- Vaccines should be stored in the pharmaceutical refrigerator which should not be overfilled to allow air to circulate around the packages
- **Domestic refrigerators should not be used for vaccine storage**
- Vaccine should be stored in their original packaging between +2^o and +8^o Celsius. This ensures that information is retained on batch numbers, expiry dates and also protects vaccines from light and heat
- The vaccine refrigerator should be placed in
 - o An appropriately ventilated room
 - o Away from any heat source
 - o Away from direct sunlight
- Manufacturer's recommendations on vaccine storage should be observed
- Vaccines should not be stored on the shelves or storage compartments of the door of non pharmaceutical refrigerators
- Vaccines that have been delivered most recently should be placed behind vaccines already in the refrigerators to ensure vaccine rotation
- The vaccine packs should not touch the sides or back of the refrigerator
- Door opening should be kept to a minimum

- A maximum/minimum thermometer should be used in refrigerators where vaccines are stored, irrespective of whether the refrigerator incorporates a temperature indicator dial. This should be placed in the middle of the refrigerator adjacent to the vaccines
- The maximum and minimum temperatures reached should be monitored and recorded at least once each working day. A sample audit form is outlined in Appendix 7.
- The maximum and minimum temperature recordings should be kept indefinitely
- Digital thermometers are the most reliable
- Thermometers should be reset, calibrated and replaced according to manufacturer's guidance
- Temperature record logs should be close to the refrigerator for ease of reference.
- The vaccine refrigerator should be cleaned every two months with a 1:10 solution of sodium hypochlorite. Vaccines should be stored in another refrigerator or cool box whilst doing this
- Care should be taken to ensure that the electricity supply to the vaccine storage refrigerator cannot be accidentally interrupted. This can be achieved by using a switchless socket or by placing cautionary notices on plugs and sockets
- Food and drink must not be stored in refrigerators used for vaccines.

5.4 Transport of vaccines to outlying clinics

In certain circumstances it may be necessary to transport vaccines to an alternative clinic or school setting. In this instance validated cool boxes (with maximum- minimum thermometers) and ice packs should be purchased from a recognised medical supply company. Domestic cool boxes must not be used.

The vaccines should be transported in their original packaging, wrapped in bubble-wrap and placed in cool box as per manufacturer's instructions.

5.5 Procedures following breakdown in the "Cold Chain"

A break down in the "Cold Chain" most commonly occurs due to a problem with the vaccine refrigerator. This may occur if there has been an electricity power cut, switch is turned off or if the refrigerator door has been left open.

If this happens

- Make sure that the refrigerator door is secured
- Find out how long the refrigerator breakdown has been and check the temperature
- Contact the Chief Pharmacist, National Immunisation Office for further advice. He/She can be contacted at **087 9915452** or **01 8676108**

Any vaccine that has not been stored at a temperature of +2⁰-+8⁰C as per licensing conditions is no longer a licensed product.

Vaccines that are outside the recommended storage temperatures must not be used and must be returned to the National Cold Chain Delivery Service as per instructions from cold chain service.

5.6 Disposal of Vaccines

- Vaccines that have been drawn up must be used within the recommended period, varying from one to four hours, according to the manufacturer's instructions
- Single dose containers are preferable, as once opened, multidose vials must not be kept after the end of the session
- Any **opened** vaccine, spent or partly spent vials must be disposed of safely in a sharps box for incineration
- At the end of an immunisation session unused vaccines must be disposed of in a puncture-resistant "sharps" box
- Sharps boxes must be securely closed when two-thirds full and placed in a secure locked room to await collection
- Contaminated waste and spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate
- **Unused unopened** vaccines which have expired or have been kept outside 2-8°C should be returned to the HSE National Cold Chain Delivery Service at the next delivery.

5.7 Useful resources

American Academy of Paediatrics. 2006 Report of the Committee on Infectious Diseases –The Red Book <http://aapredbook.aappublications.org/>

Australian Government Department of Health and Ageing National Vaccine Storage Guidelines 2005, Strive for 5 <http://www.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>

Centre for Disease Control. Vaccine management, Handling and Storage details for vaccines. http://www.cdc.gov/vaccines/programs/vfc/downloads/vacc_mgmt_guide_utah.pdf.

Department of Health UK. November 2006. Immunisation against infectious disease. http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254

Irish Pharmaceutical Healthcare Association Medical Compendium. <http://www.medicines.ie>.

Irish Medicines Board. <http://www.imb.ie>.

National Immunisation Office Ireland. Health Service Executive. <http://www.immunisation.ie>.

Public Health Agency Canada. National Vaccine Storage and Handling Guidelines for immunisation providers 2007. <http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php>.

Royal College of Physicians of Ireland. Immunisation Guidelines for Ireland. Available at www.hpsc.ie

