



HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes

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Table of Contents:

1.0	Policy	3
2.0	Purpose	3
3.0	Scope	3
4.0	Legislation/other related policies	3
5.0	Membership of Development Group	4
6.0	Membership of Governance Group	4
7.0	Communication and Dissemination	4
8.0	Training	4
9.0	Monitoring, Audit and Evaluation	4
10.0	Glossary of Terms and Definitions	4
11.0	Roles and Responsibilities	5
11.1	Roles	5
11.2	Responsibility	5
12.0	Standard Operating Procedures	5
12.1	Cool box and ice packs/gel packs specifications	6
12.2	Cool Box Maintenance of cold chain	7
12.3	Vaccine Storage and Monitoring	8
References:		11
APPENDICES		12
Appendix I: Membership of Development Group		12
Appendix II: Membership of Governance Group		12
Appendix III: Audit Tool - Cool Box		13
Appendix IV: Cold chain breaches and Light exposure		14
Appendix V: Temperature recording chart		15
Appendix VI: Contact details – National Immunisation Office		16

1.0 Policy

It is HSE National Immunisation Office (NIO) policy to maintain vaccines within the cold chain in vaccine cool boxes.

2.0 Purpose

The purpose of this guideline is to define the Standard Operating Procedures (SOPs) for the maintenance of the cold chain in HSE vaccine cool boxes e.g. in the Schools Immunisation Programme.

The purpose of this document is to:

- Ensure that potency and efficacy of vaccines is maintained i.e. compliance with their Marketing Authorisation.
- Outline procedures for management of breaks in cold chain.

3.0 Scope

All medical, nursing and administrative staff involved in handling vaccines e.g. for the Schools Immunisation Programme should follow the SOPs drawn up locally/regionally based on these guidelines.

4.0 Legislation/other related policies

- Vaccines are prescription-only medicines (POMs) and, to maintain their licensed usage, should be stored and transported in accordance with the manufacturer instructions (PIL/SmPC) and in compliance with the cold chain i.e. between +2°C and +8°C.
- Health Product Regulatory Authority (2020). Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances. [ONLINE] Available at: <http://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0011-guide-to-control-and-monitoring-of-storage-and-transportation-conditions-v1.pdf?sfvrsn=4> [Accessed 12th June 2024].
- HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock.
- Guidelines and documents from other jurisdictions - refer to "References" section.



5.0 Membership of Development Group

Please see [Appendix I](#).

6.0 Membership of Governance Group

Please see [Appendix II](#).

7.0 Communication and Dissemination

The following methods will be used for communication and dissemination across HSE sites, GPs, Public Hospitals, Occupational Health sites, Private Hospitals, Retail Pharmacies, Nursing Homes, Prisons and Colleges:

- i. An online version made available on www.immunisation.ie.
- ii. National Immunisation office (NIO) emails, bulletins and X account (formerly known as Twitter).
- iii. National Cold Chain Services (NCCS) emails

8.0 Training

An e-learning training module on Storing and Managing Vaccines is available on HSELand on <https://www.hseland.ie/dash/Account/Login>.

9.0 Monitoring, Audit and Evaluation

The sites involved in a cold chain failure will be selected randomly and audited using the sample audit tool ([Appendix III](#)) to evaluate the guideline.

10.0 Glossary of Terms and Definitions

Cold-Chain: A temperature-controlled supply chain for products that require a specific temperature range during distribution and storage. Specifically, this refers to a supply chain that includes the handling, transportation, and storage of temperature-controlled products. For vaccines the recommended temperature-controlled range is between a minimum of +2°Celsius and a maximum of +8°Celsius (+2°C to +8°C).

Conditioning of ice packs/gel packs: The process of leaving ice packs/gel packs at room temperature to allow the ice or gel at the



surface of the pack to defrost and the ice core to move freely within the pack, surrounded by a melted layer. This minimises the risk of freezing the vaccines.

NCCS: National Cold Chain Service.

NIO: National Immunisation Office.

Vaccine: Any preparation intended to produce immunity to a disease by stimulating the production of antibodies. Vaccines include, for example, suspensions of killed or attenuated microorganisms, or products or derivatives of microorganisms.

11.0 Roles and Responsibilities

11.1 Roles

- Managers to ensure that staff members involved in immunisation are aware of the SOP.
- Managers to ensure that staff members involved in immunisation comply with the SOPs through monitoring, audit and review.
- HSE staff involved in immunisation to be aware of and follow the SOPs.

11.2 Responsibility

The SOPs should allocate overall responsibility for cold chain management to a designated person(s). However, each vaccinator is responsible for ensuring that the vaccines they administer have been correctly stored and are in date. The cold chain management SOPs should be dated and signed by relevant staff and reviewed on an annual basis.

12.0 Standard Operating Procedures

All vaccines are sensitive to heat, cold and light and must be kept at temperatures between **+2°C and +8°C**. Vaccines stored outside this temperature range or **exposed to either UV or fluorescent light** can result in the loss of potency (see [Appendix IV](#)).

12 Domestic cool boxes should not be used to store, distribute or transport vaccines. Cool boxes should be purchased from reputable medical equipment suppliers.

12.1 Cool box and ice packs/gel packs specifications

Solid walled or vaccine specific soft walled insulated cool boxes must be used for transporting vaccines. Ice packs/gel packs recommended by the manufacturer should be used in cool boxes unless the cool box is electrically powered with DC or AC for keeping vaccines between +2 °C and +8°C.

- i. The cool box must have a probe inside of it, which is linked to the temperature display on the outside of the cool box. This external display allows the temperature where the probe is located to be monitored without opening the box. For details on placing the probe with vaccines in the cool box see [Section 12.3 point vi](#).
- ii. The thermometer display should be accurate to +/- 0.5°C (or better) and be supplied with a certificate of calibration.

Note: Where temperature display is not built as part of the cool box a minimum/maximum temperature monitor, or a data logger with a probe attached to an extended wire placed inside the cool box can be used.

- iii. A data logger should be used in cool boxes where external temperature display records only current temperature. This will provide an accurate account of temperatures reached and the duration of any temperature breach. The information on the data logger can be downloaded at the end of a vaccination day to confirm that any returned vaccines have remained within temperature. **A data logger does not replace the need to check cool box temperatures each time when removing vaccines prior to administration.** A data logger should be set to record at 5 to 10 minute intervals.
- iv. Ice packs or Gel packs
 - a) An ice pack is a plastic container filled with water/chemicals and must be stored in accordance with manufacturers' instructions in a freezer. It should never be in direct contact with the vaccines as it will freeze the vaccines. Sufficient barrier layer of insulating material (e.g. bubble-wrap or polystyrene chips) must be used to prevent freezing.
 - b) Gel packs contain chemicals that depress the freezing point of the pack so that the gel remains cooler than 0°C for a long period. There are refrigerated and frozen gel packs which are

refrigerated at +2°C to +8°C and frozen in a freezer respectively. The conditioning process of gel packs varies depending on the type. Follow the manufacturer's instructions for conditioning gel packs.

Note: For all packing materials and equipment, ensure that the specifications of each item are adhered to in accordance with the manufacturer's guidelines. Each site should have SOPs on how to pack a cool box with the ice packs /gel packs and vaccines. The risk of freezing of vaccines in cool boxes increases if ice packs /gel packs are not correctly conditioned or separated by insulating material.

12.2 Cool Box Maintenance of cold chain

It is important to test and validate the method of packing vaccines by simulating the process and recording the cold chain for a similar period required for a typical transportation and clinic duration.

The cool box requires ice packs/gel packs to maintain the correct temperature of +2°C to +8°C (unless electric cool boxes are used which are powered with DC or AC).

In the cool box, air does not circulate to create an even temperature zone therefore **the temperature needs to be monitored at regular intervals by the user via the external display.**

The number of ice packs/gel packs required depends on the following variables:

- i. Quality characteristics of cool box and ice packs/gel packs.
- ii. Temperature and volume of ice packs/gel packs.
- iii. Volume of the vaccines and volume of the cool box- is the box full or is there a lot of space in the box?
- iv. External temperature - the warmer the ambient temperature, the more rapidly the internal temperature of the cool box will rise because the cool box is only an insulation that separates the vaccines from the temperature outside. If the cool box is being transported in the boot of a car on a warm day it will require more ice packs/gel packs than if it were a very cold day.
- v. The distance and time in transit and the duration of the clinic.



- vi. The number of times the lid will be opened and closed, as each opening will raise the temperature.

12.3 Vaccine Storage and Monitoring

Vaccines must be stored in pharmaceutical fridges at the HSE vaccine storage site in accordance with the local Vaccine Fridge Standard Operating Procedures (SOPs). The best assurance of vaccine efficacy is to minimise the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical to maintain the cold chain at all times.

Cool box temperature should be maintained between +2°C and +8°C at all times.

How to pack a cool box:

- i. Check the temperature of the vaccines being transported (i.e. fridge temperature)
- ii. Use the number of ice packs/gel packs as per cool box manufacturer's instructions and local SOP.
- iii. Place the ice packs/gel packs in the cool box for a minimum of 15 minutes (or as per manufacturers recommendations) before the vaccines are packed into the cool box.
- iv. Ice packs/gel packs must not come in direct contact with the vaccines. The packs must be sufficiently wrapped or separated by insulating material to prevent direct contact with the vaccines and to avoid the risk of freezing or the temperature to drop to less than 2°C.
- v. Position the ice packs/gel packs appropriately above, below and at the sides of the vaccines as space in the cool box allows (as recommended by the manufacturer and local SOP).
- vi. A thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent the probe from moving during transport, it can be placed in an empty vaccine box, placed in the middle of the vaccines.
- vii. Fill the empty space between the lid and the product with bubble wrap to provide an additional layer of insulation.

- viii. Shut the lid of the cool box tightly and keep the lid closed as much as possible (reducing lid opening helps to keep internal temperatures stable)
- ix. The vaccines must be transported in their original packaging.
- x. Only the number of vaccines estimated for administration on any particular day should be brought to the site.
- xi. Ensure the appropriate vaccines are packed which are in date and where possible from one batch.
- xii. It may be necessary to add/remove ice packs or gel packs as the temperature dictates.
- xiii. Record the temperature in the cool box (See [Appendix V](#) for sample Temperature recording chart):
 - when vaccines are packed,
 - upon arrival at the immunisation clinic,
 - throughout the immunisation clinic,
 - when returning vaccines to the fridge.

Note: Where frozen ice/gel packs are used, freezing can occur in a cool box, with the greatest risk within the first 2 hours after packing. Monitor and record the maximum/minimum and current temperature frequently for the first 2 hours. Where current temperature reading only is available, this should be done every 15 minutes. Where maximum/minimum readings are available, and providing the temperature is not dropping to +2°C or lower, then less frequent recording is acceptable. Thereafter, once temperatures are stable, hourly readings of the external display should be recorded.

- xiv. The cool box should be placed in,
 - An appropriately ventilated room,
 - Away from any heat source,
 - Away from direct sunlight.
- xv. The cool box should remain closed as much as possible.
 - Only the amount of vaccine needed at one time should be removed for preparation and administration.
 - The temperature inside the cool box must be monitored.
- xvi. If there are any unused vaccines remaining at the end of a vaccination session, providing that the cold chain has been maintained, the vaccines can be returned to the vaccine fridge.



They must be marked and should be used first at the next vaccination session.

If these marked vaccines are taken to a second vaccination session and are not used -they **can** be returned to the vaccine fridge, and administered at the next clinic **provided the cold chain has been maintained.**

- xvii. Record the temperature of the vaccine being returned to the vaccine fridge and the time of return ([Appendix V](#)).
- xviii. The cool box thermometer / data logger should be calibrated on an annual basis, in accordance with the manufacturer guidelines. A validated cool box provides ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport. With time and use, cool boxes and ice packs /gel packs may no longer be able to maintain the temperature range for extended periods so monitoring is always required. The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours.
- xix. Vaccines **exposed to either UV or fluorescent light** can lose potency. Any vaccine that has been removed from its packaging should be used within the time specified in PIL/SmPC. It should not be returned to the cool box but discarded safely into a sharps bin. The sharps bin should be securely sealed when three-quarters full or filled to the manufacturer's fill line.
- xx. Reconstituted vaccines lose potency even when stored between +2°C and +8°C. The potency loss depends on the vaccine and the length of time since reconstitution. For manufacturer's recommendations after reconstitution refer to PIL/SmPC.
- xxi. Check that the temperature has remained between +2°C and +8°C before administering a vaccine
- xxii. If temperatures outside the permitted range are recorded, first check the position of the temperature probe. The temperature probe should be in a vaccine box in the middle of the vaccines – if it is not correctly positioned reset the probe and ensure it is positioned correctly away from ice packs/gel packs or lid of cool box then close the box firmly and recheck the temperature in 15 minutes.
- xxiii. If the temperature is still outside the permitted range, place the



vaccines under quarantine between +2 and +8 °C in the fridge or another cool box (if available), and contact the NIO for further advice (e-mail pharmacynio@hse.ie). The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded.

- xxiv. **Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until advised by the National Immunisation Office.**

References:

1. Australian Government Department of Health. National Immunisation Program (2019). National Vaccine Storage Guidelines – Strive for 5, 3rd edition. [ONLINE] Available at: <https://www.health.gov.au/sites/default/files/documents/2020/04/national-vaccine-storage-guidelines-strive-for-5.pdf> [Accessed 12 June 2024]
2. BC Centre for Disease Control (2020). Vaccine Storage and Handling Course. [ONLINE] Available at: <http://www.bccdc.ca/health-professionals/education-development/immunization-courses/vaccine-storage-and-handling-course>. [Accessed 12 June 2024].
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5. Ontario Ministry of Health and Long-Term Care (2018). Vaccine Storage and Handling Protocol. [ONLINE] Available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/Vaccine_Storage_and_Handling_Protocol_2018_en.pdf [Accessed 12 June 2024].
6. Ottawa: Public Health Agency Canada (2015). National Vaccine Storage and Handling Guidelines for Immunization Providers 2015. [ONLINE] Available at: <https://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/alt/vaccine-storage-entreposage-vaccins-eng.pdf> [Accessed 12 June 2024].

National Immunisation Office website: www.immunisation.ie

- HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock - available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>
- HSE vaccine return form is available at www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvaccreturn.pdf

APPENDICES

Appendix I: Membership of Development Group

Name	Title	Organisation
Cora Kerrigan	Chief Pharmacist	National Immunisation Office
Achal Gupta	Chief II Pharmacist	National Immunisation Office
Leah Gaughan	Senior Pharmacist	National Immunisation Office

Appendix II: Membership of Governance Group

Name	Title	Organisation
Dr Lucy Jessop	Consultant in Public Health Medicine – National Immunisations Lead	National Immunisation Office

Appendix III: Audit Tool - Cool Box

Site ref. no :		Audit undertaken by:	
Date :		Grade/Title:	

Please tick (x) the relevant box

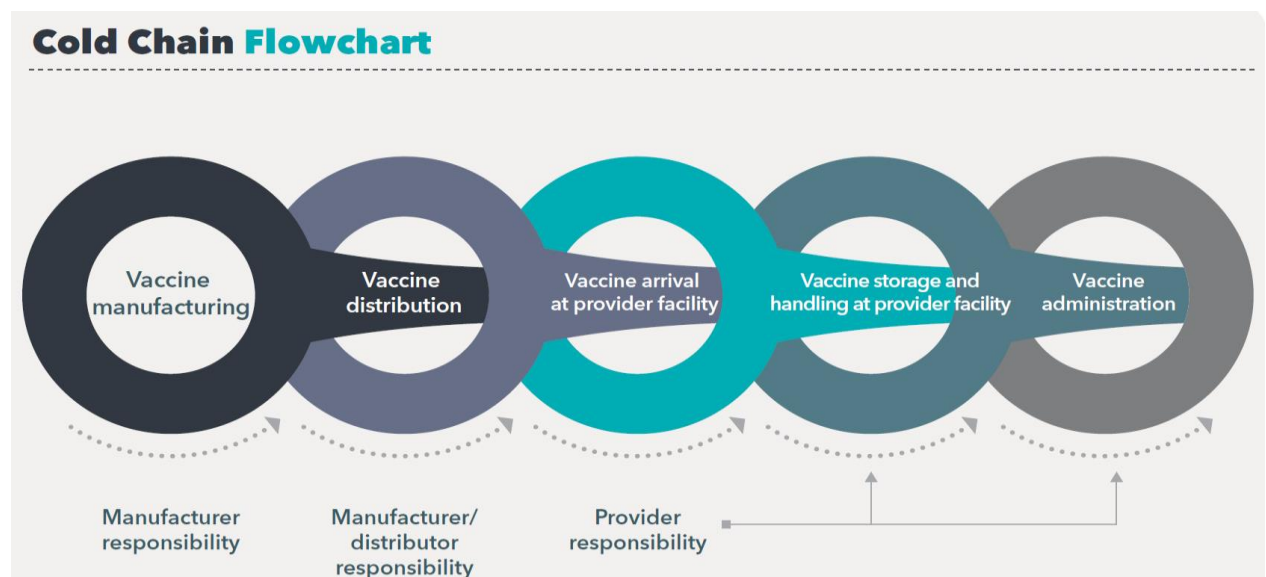
	Equipment/Records	Yes	No	n/a
1	Is cool box along with ice packs/gel packs (unless electric cool boxes are used which are powered with DC or AC) available for transporting vaccines to the immunisation site?			
2	Are there SOPs in place for the maintenance of the cold chain in vaccine cool boxes?			
3	Are annual certified calibration records of cool box thermometer available? (please check last 2 year records)			
4	Are annual certified calibration records of data-logger available? (please check last 2 year records)			
	Responsible Person/Procedures			
5	Is the person responsible for packing and transporting vaccines familiar with the HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes?			
6	Is the person responsible for packing and transporting vaccines aware of the following:			
<i>A</i>	The risk of vaccines freezing in cool boxes increases if ice packs/gel packs are not correctly conditioned or separated by insulating material?			
<i>B</i>	Thermometer probe (and/or data logger) should be placed in the middle of vaccines?			
<i>C</i>	That any vaccine that has been removed from its packaging and not used within the time specified in PIL/SmPC should be discarded?			
<i>D</i>	The actions to be taken if the temperature falls outside +2°C to +8°C (i.e. breakdown in the "Cold Chain")?			

Appendix IV: Cold chain breaches and Light exposure

Vaccines are delicate biological substances that can become less effective or destroyed if they are:

- frozen
- stored above +8°C
- exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light.

The **cold chain** (storage between +2°C and +8°C) begins at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient. If the cold chain is not maintained, vaccine potency and efficacy may be reduced or lost, resulting in administration of a sub-optimal vaccine. This can require revaccination of patients which will increase cost for providers/ taxpayers and damage the public confidence in vaccines.



Cold Chain Flowchart - Centers for Disease Control and Prevention (2019). Vaccine Storage and Handling Toolkit.

Exposure to conditions outside the parameters of +2°C to +8°C can affect potency of vaccines, but a single exposure to freezing temperatures (0°C or below) can destroy potency.

NOTE: Vaccines should be kept in fridge/cool box in their original packaging until they are administered, to prevent damage from light and ambient temperature.



Appendix VI: Contact details – National Immunisation Office

Title/Organisation	Email
Pharmacists, National Immunisation Office	pharmacynio@hse.ie
Clinical Query Team - National Immunisation Office	immunisation@hse.ie