



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



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

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1.0 Policy

It is HSE National Immunisation Office (NIO) policy to maintain vaccines within the cold chain in HSE 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 box 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 Glossary of Terms and Definitions

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.

The "**Cold-Chain**" is 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 product. 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).

NCCS National Cold Chain Service

NIO National Immunisation Office

5.0 Roles and Responsibilities

5.1 Roles

- Managers to ensure that all members of staff involved in immunisation are aware of the SOP.
- Managers to ensure that all members of staff 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.

5.2 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. The cold chain management Standard Operating Procedures should be dated and signed by relevant staff and reviewed on an annual basis.

6.0 Standard Operating Procedures

All vaccines are sensitive to heat, cold and light and must be kept at temperatures between +2°C to +8°C. Leaving vaccines outside this temperature range or exposed to either UV or fluorescent light can result in the loss of potency.

Domestic cool boxes should not be used to store, distribute or transport vaccines.

6.1 Cool box and Packs specifications

Validated cool boxes and cool packs or ice packs must be used.

1. The cool box must have a probe in the box which is linked to the temperature display on the outside of the box so that the temperature where the probe is located can be monitored without opening the box.
2. The thermometer display should be accurate to +/- 0.5°C (or better) and be supplied with a certificate of calibration.
3. A battery powered continuous temperature recording device (data logger) may be used in cool boxes where vaccines are stored. This should be removed from the vaccine fridge with the vaccines and placed in the middle of the cool box adjacent to the vaccines. This is

an independent device and gives an accurate account of the 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. This does not replace the need to check cool box temperatures each time when removing vaccines prior to administration.

4. Cool packs or Ice packs

- a) Cool packs must be stored in accordance with the manufacturers' instructions, at +2°C to +8°C to ensure they maintain the cold chain at the right temperature.
- b) Ice packs must be stored in accordance with manufacturers' instructions in a freezer. These should never be in direct contact with the vaccines as they will freeze the vaccines. Sufficient barrier layer must be used to prevent this happening.

6.2 Cool Box Maintenance

It is important to test and validate the method of packing vaccines in order to maintain the cold chain during transportation and duration of clinic. As the box does not cool, it relies on cool/ice packs to achieve the correct temperature and maintain the temperature within the +2°C to +8°C parameters. Ensure that everything is cooled prior to packing to avoid temperature fluctuations.

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 cool/ice packs required depends on the following variables:

1. Temperature of the cool packs
2. Volume of cool/ice packs
3. Volume of the vaccines and volume of the cool box- is the box full or is there a lot of space in the box?
4. External temperature - the warmer the ambient temperature, the more rapidly the internal temperature will rise because the cool box is only an insulation that separates the vaccines from the outside temperature. If the box is being transported in the boot of a car on a warm day it will require more cool/ice packs than if it were a very cold day.

5. The distance and time in transit and the duration of the clinic
6. The number of times the lid will be opened and closed, as each opening will raise the temperature.

6.3 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

1. Use the number of cool packs or ice packs as per cool box manufacturer's instructions/best practice recommendations.
2. Ice packs or frozen cool packs must not come in direct contact with vaccine. They must be sufficiently wrapped to prevent the vaccine from freezing i.e. exposure to temperature less than 2°C.
3. Place the cool packs or ice packs in the cool box for a minimum of 15 minutes before the vaccines are packed into the cool box.
4. Position the cool packs or ice packs appropriately above, below and around the vaccines as space in the cool box allows.
5. Only the number of vaccines estimated for administration on any particular day should be brought to the site.
6. The vaccines must be transported in their original packaging.
7. Ensure the appropriate vaccines are packed which are in date and where possible from one batch.
8. Record the temperature of the vaccines being transported (i.e. fridge temperature) at the time of packing.
9. Place the temperature probe into a vaccine box, which should be placed in the middle of the vaccines. Record the temperature of the cool box.

10. Fill the empty space between the lid and the product with bubble wrap to provide an additional layer of insulation.
11. Shut the lid of the cool box tightly.
12. It may be necessary to add/remove cool packs or ice packs as the temperature dictates.
13. Record the temperature in the cool box, (e.g. see Vaccination Session Report Forms in the Guidelines for Staff: Schools Immunisation Programme 2016/2017)
 - Before leaving the HSE vaccination storage site.
 - At the beginning of the vaccination session.
 - At the end of the vaccination session.
 - On returning the vaccines to the fridge.
14. The cool box should be placed in,
 - An appropriately ventilated room,
 - Away from any heat source,
 - Away from direct sunlight.
15. 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.
16. 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 on their next vaccination session.

If these marked vaccines are taken to a second vaccination session and are not used **providing the cold chain has been maintained**, these vaccines **can** be returned to the vaccine fridge again, for administration at the next session.

If a temperature deviation has occurred, contact the Chief Pharmacist or the Medical Officer of the National Immunisation Office (at 087 9915452 or 01 8676108) for further advice. The National Immunisation Office will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines later or whether they should be discarded.

17. Temperature of the vaccine being returned to the vaccine fridge should be recorded and record the time of return.

18. The cool box thermometer should be sent back to the manufacturer for calibration on an annual basis. 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/ cool 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.
19. Any vaccine that has been removed from its packaging and is not used in a timely manner should not be returned to the cool box but should be discarded safely into a sharps bin.

MMR vaccines must be used within one hour of reconstitution or discarded safely into a sharps bin – it is not appropriate to return reconstituted MMR vaccine to the cool box.

Once 4 in 1, Tdap and HPV which come in prefilled syringes are removed from their packaging they should be used at that vaccination session or discarded safely into a sharps bin.

20. 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 or at the lid of cool box then close the box firmly and recheck the temperature in 15 minutes.
21. If the temperature is still outside the permitted range the Chief Pharmacist or the Medical Officer of the National Immunisation Office should be contacted (at 087 9915452 or 01 8676108) for further advice. The National Immunisation Office 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.
- 22. 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 +8°C until advised by the National Immunisation Office.**

References

- Centers for Disease Control and Prevention – immunisation information available at <http://www.cdc.gov/vaccines/>

Public Health Agency of Canada

<http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php>

Guidelines for Staff: Schools Immunisation Programme 2016/2017 available at

<http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>

- Health Protection Scotland. Guidance on Vaccine Storage and Handling (Version 2.0 August 2013) Available at <http://www.hps.scot.nhs.uk/Search/guidedetail.aspx?id=45674>

HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines

<http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/SOP2016.pdf>

Immunisation Guidelines for Ireland available at

<http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines>

- National Immunisation Office available at <http://www.immunisation.ie>

- New Zealand, Ministry of Health immunisation website available at <http://www.moh.govt.nz/immunisation>

HSE vaccine order form is available at

<http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hseorderform.pdf>

HSE vaccine return forms are available to download from

<http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hsevaccreturn.pdf>