



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock

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1.0 Policy

It is HSE National Immunisation Office (NIO) policy to maintain vaccines within the cold chain in vaccine fridges and also to manage vaccine stock in accordance with best practice.

2.0 Purpose

The purpose of these guidelines is to define the Standard Operating Procedures (SOPs) for the maintenance of the cold chain in vaccine fridges and vaccine stock management, at HSE vaccine storage sites.

The purpose of this document is to

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

3.0 Scope

All medical, pharmaceutical, nursing and administrative staff involved in handling HSE supplied vaccines should follow the SOPs drawn up locally/regionally based on these guidelines. (These SOPs should include details of the designated staff member and the alternative member of staff who covers in their absence - a minimum of 2 people).

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°C and a maximum of +8°C (+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 staff members are aware of the SOPs.
- Managers to ensure that staff members 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 SOPs 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 can result in the loss of potency.

6.1 Vaccine Storage

Vaccines should only be stored in **PHARMACEUTICAL FRIDGES** and **ONLY** vaccines should be stored in this fridge.

Domestic fridges should **NOT** be used for vaccine storage.

Pharmaceutical fridges will have at least the following specifications:

1. Features either solid or glass door which is lockable.
2. Maintains internal air temperature between +2°C and +8°C and the temperature can be read externally.
3. Fully automatic defrosting.
4. Fan operated, forced air cooling for temperature stability.

5. Integral controller enabling staff to set the required temperature and easily monitor and record current/minimum/maximum levels.
6. Both audio and visual alarm signal when temperature deviation lasts for more than 15 minutes.
7. Open door sensor which alerts the user that the fridge door is not properly closed and sealed.
8. Large enough to hold 6 weeks inventory.

IMPORTANT NOTE:

When a new pharmaceutical fridge is installed in its permanent position or when a fridge is moved, it should be allowed to stand for minimum of 24 hours before it is switched on. This allows gases to reach equilibrium before power is switched on. Then record the temperature for 48 hours to ensure it is maintaining the correct temperature.

The fridge should be levelled in a way that allows the door to close and seal automatically if left ajar.

6.2 Vaccine Fridge Maintenance and Monitoring

1. The fridge should be placed in an appropriately ventilated room away from any heat source and away from direct sunlight.
2. Fridge temperatures (current, maximum and minimum) should be recorded twice daily, at the start and end of each day during the working week. It is important to record the maximum and minimum temperature every morning (especially after the weekend or any other time when the vaccine storage site has been closed for a day or more) before any vaccines are administered.

The maximum/minimum reading should be cleared from fridge memory and reset after each reading. To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these three readings should all show the same temperature (i.e. current temperature). It is important to reset the fridge thermometer at the end of a clinic if the fridge door has been opened on several occasions, if the fridge has been re-stocked or cleaned and at the start and end of every day. Resetting should be

carried out once the current temperature reading has returned to within the recommended range.

3. A data logger (a battery powered continuous temperature recording device) should be used in fridges where vaccines are stored. This should be placed in the middle of the fridge adjacent to the vaccines. This device is independent of the fridge and continues to record the temperatures even when there is no power supply and therefore gives an accurate account of the temperatures reached and the duration of any temperature breach.

The data logger should be downloaded regularly (at least once every two weeks) and the electronic or printed record should be retained indefinitely. The stored data will suffice as a permanent temperature record for the fridge.

Once a temperature breach is registered by fridge thermometer (current, maximum or minimum) or fridge has alarmed the data logger should be downloaded to ascertain the temperatures reached and the duration of the breach.

The data logger does not replace reading the fridge temperatures (current, maximum and minimum) twice daily.

4. A temperature monitoring chart should be on each vaccine fridge door. (Appendix 1) This chart should record maximum, minimum and current temperature twice daily. When a temperature record has been completed, replace it with a new record and keep completed records close to the fridge. These records should be stored securely indefinitely, unless data logger records are being retained.
5. The door should remain closed as much as possible and staff should keep door opening to a minimum. Reducing door openings helps to keep internal temperatures stable. Check that the doors are properly sealed by giving a gentle tug on the door handle. The doors should also be checked at the end of each day to make sure that they are properly closed and sealed.

When loading the fridge, vaccine removal, fridge cleaning or stock rotation, door openings may cause the air temperature in the fridge to increase up to room temperature for a short time. Once the fridge door is closed the temperature should drop to between +2°C and +8°C within 15 minutes.

After such a period of high activity maximum temperature should be recorded and memory erased. A note on the temperature recording record (Appendix 1) should indicate the cause of the increase in temperature e.g. vaccine removal.

If the temperature does not return to between +2°C and +8°C within 15 minutes the Chief Pharmacist or Medical Officer National Immunisation Office should be contacted (Phone 087 9915452 or 01 8676108) for further advice.

6. Containers of water can be placed in spaces at the sides or on empty shelves in the fridge to help maintain the temperature. This may arise if there is a planned power outage and/ or when the fridge is not full.
7. Prevent interruptions to the electricity supply to the vaccine fridge. This can be achieved by directly wiring the fridge to the electricity supply without using a plug and using a dedicated circuit for the fridge and also label the fuse. Avoid using plugs that can be activated by a wall switch. Where this is not possible arrangements should be put in place to ensure the plug is never pulled out, and the switch is never turned off (these arrangements could include difficult access to the socket e.g. behind the fridge or physical cover) or by placing cautionary notices on plugs and sockets e.g. "Don't unplug me" stickers are available from the NIO.
8. The fridge should be kept clean and dust free at all times. Any dust should be removed from the coils. The inside of the fridge should be regularly cleaned with warm slightly soapy water. Dry thoroughly and only restock once the temperature is within the recommended range.
9. The fridge seals should be regularly inspected. The seal should not be torn or brittle and there should be no gaps between the seal and the body of the unit when the door is closed. Check the seal by placing a thin strip of paper against the door seal, close the door and pull the strip. If the paper falls or comes away easily, then the seal needs to be replaced or adjusted. Check all around the door and particularly the corners.
10. The fridge should be serviced and thermometers calibrated annually. Records of servicing and cleaning should be maintained.

11. Contaminated wastage or spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate.
12. Vaccine storage procedures should be audited at least 12 monthly or more frequently if experiencing cold chain problems.
13. Ensure that **adequate insurance for vaccine damage is in place** in case of fridge breakdown to allow for vaccine replacement.

REMEMBER THE 4Rs

Read: Twice daily readings of the fridge thermometer's maximum, minimum and current temperatures at the same time morning and evening daily during the working week.

Record: record fridge temperatures in a standard fashion and on a standard form stating date and time of reading and sign/initial (Appendix 1) and download data logger regularly.

Reset: reset the fridge thermometer after each reading and/or when temperatures have stabilised after a period of high activity and at the end of every day.

React: the person making the recordings should take action if the temperature falls outside +2°C to +8°C and document this action (Appendix 3).

6.3 Vaccine Stock Management

6.3.1 Vaccine ordering

1. Vaccine stocks should be kept to a minimum by regularly ordering only the quantity of vaccine required until the next delivery. The designated person should know how much vaccine stock they require at any one time, according to the size of the target population.
2. A "vaccine stock sheet" (Appendix 2- HSE Sites) should be kept to record the date and stock on hand, stock used and quantity ordered to facilitate monthly ordering. Online ordering facilitates stock recording. A minimum vaccine stock of two weeks supply but no more than six weeks should be kept. Overstocking can lead to wastage in the event of cold chain failure or due to expiry date being reached or increase the risk of administering an expired vaccine.

3. Vaccines should be ordered online, by emailing or faxing to the HSE National Cold Chain Service (NCCS)
 - i. Online: <https://www.ordervaccines.ie/login.aspx>
 - ii. E-mail vaccines@udd.ie
 - iii. Fax number (01) 4637788
4. The order form is available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hseorderform.pdf>
5. The NCCS send a confirmatory email/fax outlining that they have received the order and confirming the vaccine delivery date. If this email or fax is not received the NCCS should be contacted directly.
6. Vaccines should be ordered by a specific date each month as per a prescribed schedule from the NCCS.

6.3.2. Accepting Vaccine deliveries

1. Vaccine deliveries must be signed for and must be checked against the order for discrepancies. Any discrepancies or any damage must be reported to the NCCS immediately.
2. Vaccines must be placed **immediately** in the vaccine fridge and must **never** be left at room temperature.
3. The temperature on delivery should be checked and recorded to show that vaccines were in temperature on delivery.
4. Vaccines must be removed from delivery box, checked against delivery docket, allocated to appropriate area in fridge and recorded.
5. The delivery docket should be filed as it contains details of the delivery, batch number and expiry dates of products.

6.3.3. Vaccine storage, usage, stock rotation and disposal

1. Vaccines should always be stored in the fridge in their original packaging. This packaging protects them from light and heat, and this box carries the appropriate batch number and expiry date, which is required for recording. Vaccines should not be removed from their packaging until required for use. The deleterious effects of light exposure on light sensitive vaccines are cumulative.

2. Vaccine boxes must not touch the sides, back or bottom of the fridge. Air needs to circulate around the packages therefore the fridge should not be overfilled, as this will prevent proper airflow.
3. Expiry dates of vaccines should be regularly checked and vaccine stock should be rotated so that vaccines with the shortest expiry date are closest to hand. Vaccine with the shortest expiry date should be used first.
4. Once opened multi-dose vials must not be kept after the end of the session.
5. Opened vaccine vials either empty or partly used should be disposed of safely into a sharps bin. They should not be returned to the NCCS.
6. Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the NCCS deliveryman with a completed vaccine return form. A copy of this should be retained locally. Vaccine return forms are available to download from <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvaccreturn.pdf> Expired and damaged unopened vaccines **must not** be put into a sharps bin.

6.4 Procedure following breakdown in the "Cold Chain"

In accordance with product licence, all vaccines must be stored in a fridge between +2°C and +8°C and must not be frozen.

A breakdown in the "Cold Chain" occurs when vaccines are NOT stored between +2°C and +8°C.

This can be due to delay in refrigerating vaccines once delivered, faulty fridge, electrical power cut, fridge unplugged /switched off, or fridge door left open.

If there is a breakdown in the "Cold Chain":

1. Check the temperature on the fridge thermometer (current, maximum and minimum), note the time and remove the continuous temperature recording device (data logger) to download the readings and return to fridge.
2. Ensure that the fridge door is closed and fridge is working. If the fridge is not working or not holding temperature between +2°C and +8°C then move vaccines to a working fridge immediately if another fridge is available.

3. Determine how long the fridge has been outside temperatures between +2°C and +8°C by downloading the continuous temperature recording device, or other means.
4. Record the date and time and nature of the breakdown (Appendix 3).
5. Record the type quantity and batch numbers of vaccines (Appendix 4) in each fridge affected by the incident.
6. If temperatures outside the permitted range are recorded the Chief Pharmacist or Medical Officer National Immunisation Office should be contacted (Phone 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.
7. Vaccines affected by a break in the cold chain must, identified with a sticker reading "DO NOT USE," and quarantined in the fridge between +2°C and +8°C separated from vaccines which were not exposed to a breach.
8. **Do not use or dispose of any vaccine and keep vaccines between +2°C+8°C in quarantine until advised by the National Immunisation Office.**
9. Vaccines that cannot be used must be removed from the fridge, details on the returns form completed and returned to the NCCS on the next delivery day. A copy of this should be retained locally. The HSE vaccine returns form is available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvaccreturn.pdf>

If the vaccine fridge has electrical problems record the temperature for 48 hours before using the fridge to store a new supply of vaccines.

When a new **pharmaceutical** fridge is installed in its permanent position or when a fridge is moved, it should be allowed to stand for minimum of 24 hours **before** it is switched on. This allows gases to reach equilibrium before power is switched on. Then record the temperature for 48 hours to ensure it is maintaining the correct temperature. The fridge should be levelled in a way that allows the door to close automatically if left ajar.

References

- Centers for Disease Control and Prevention – immunisation information available at <http://www.cdc.gov/vaccines/>
- 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 in vaccine cool boxes. <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopcoolboxes2016.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/gpvaccreturn.pdf>

- **Appendices**

Appendix 1:

Temperature Log

- 1. Record the current temperature and the minimum/maximum fridge temperature twice daily: when you first open the office and before closing.
- 2. Remember to reset your min-max fridge thermometer after recording the temperatures.

Month: _____ Year 20		Fridge number: _____				Location: _____				Note factors which may affect fridge performance e.g. door opening, vaccine delivery
Day of the Month	Name/Initial	AM Time	Current C°	Min C°	Max C°	PM Time	Current C°	Min C°	Max C°	
1										
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Appendix 4:
Vaccines involved in "Cold Chain" breakdown

VACCINE	TRADE NAME	BATCH NUMBER	EXPIRY DATE	QUANTITY
<u>School Immunisation Programme</u>				
BCG				
Tuberculin				
DTaP/IPV (4in1)				
Tdap /IPV(4in1-low dose)				
MMR				
HPV				
Tdap				
Meningococcal C (MenC)				
<u>Primary Immunisation Programme</u>				
DTaP/IPV/HIB/HepB (6in1)				
Hib (Haemophilus Influenza Type B)				
Hib/MenC				
Meningococcal B (MenB)				
Meningococcal C (MenC)				
MMR				
Pneumococcal Conjugate Vaccine (PCV)				
Rotavirus				
<u>Seasonal</u>				
Influenza Vaccine				
Pneumococcal Polysaccharide Vaccine (PPV)				
<u>Others</u>				
Hepatitis B Renal (higher dose)				
Hepatitis B Adult				
Hepatitis B Paediatric				
Hepatitis A Adult				
Hepatitis A Paediatric				
Hepatitis A and B Adult				
Hepatitis A and B Paediatric				
MenACWY				
Td				
Tdap				