Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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

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1.0 Policy

It is HSE National Immunisation Office 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.

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°Celsius and a maximum of +8°Celsius (+2°C to +8°C).

NCCS National Cold Chain Service

UDD United Drug Distributors

5.0 Roles and Responsibilities

5.1 Roles

- Managers to ensure that employees are aware of the SOPs.

- Managers to ensure that employees comply with the SOPs through monitoring audit and review.

- HSE employees 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 glass or solid 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 minimum/maximum levels.

6. Audio/visual alarm signal when temperature deviation lasts for more than 15 minutes.

7. Open door sensor which alerts the user that the fridge has been left open.

When a new **pharmaceutical** fridge is placed in its permanent position, 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.

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

3. Vaccine boxes should not touch the sides or back of the fridge. Air needs to circulate around the packages, therefore the fridge should not be overfilled.

4. Vaccines should always be stored 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.

5. Fridge temperatures (current, maximum and minimum) should be recorded twice daily, at the start and end of each day. The maximum/minimum reading should be cleared from memory after each reading. If there is a battery powered continuous temperature recording device (data logger) present in the fridge, then only the current temperature is required to be read daily before any vaccines are administered.

   The data logger should be downloaded regularly and stored data will suffice as a temperature record. Once a temperature breach is registered by fridge or fridge has alarmed down load the data logger to ascertain the temperatures reached and the duration of the breach.

The data logger does not replace reading the fridge thermometer daily unless it is downloaded daily before any vaccines are administered.

Data loggers should be used in fridges where vaccines are stored, irrespective of whether the fridge incorporates a temperature indicator dial. 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.

6. A temperature monitoring chart should be on each vaccine fridge door. (appendix 1) Daily readings should be recorded on this chart where a data logger is in place. If not data logger is being used 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 record indefinitely.

7. The door should be closed as much as possible. Vaccine fridges should have a sticker to remind staff to keep opening to a minimum. Reducing door openings helps to keep internal temperatures stable.

8. Containers of water can be placed in the refrigerator to help stabilise the temperature in the unit. This may arise if there is a planned power outage and the fridge is not full.

9. The electricity supply to the vaccine storage fridge should not be accidentally interrupted. This can be achieved by directly wiring the fridge to the electricity supply without using a plug. 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 refrigerator or physical cover) or by placing cautionary notices on plugs and sockets "Vaccine Refrigerator", "Do not turn off or disconnect".

10. The fridge should be kept clean and dust free at all times. 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.

11. The fridge should be serviced and thermometers calibrated annually. It should be regularly cleaned with a 1:10 solution of sodium hydrochloride (or dilute Milton).

12. Records of servicing and cleaning should be maintained.

13. Contaminated wastage or spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate.

14. Vaccine storage procedures should be audited at least 12 monthly or more frequently if experiencing cold chain problems.

15. Ensure that adequate insurance for vaccine damage is in place in case of fridge breakdown to allow for vaccine replacement.

REMEMBER THE 4Rs

Read: daily readings of the fridge thermometer's maximum, minimum and current temperatures at the same time every day during the working week (or daily readings of current temperature where a data loggers is in place)

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

Reset: reset the thermometer after each reading. The thermometers should also be reset when temperatures have stabilised after a period of high activity. The maximum/minimum thermometer should be re-set by clearing the thermometer memory 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 should all show the same (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 or if the fridge has been re-stocked or cleaned. Resetting should be carried out once the current temperature reading has returned to within the recommended range. This is very important where there is no data logger in place.

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

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. A "vaccine stock sheet" (See Appendix 2) should be kept to record the date and stock on hand and quantity ordered to facilitate monthly ordering. 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.

2. Vaccines should be ordered by emailing or faxing the HSE National Cold Chain Service (NCCS) (current contract holders are United Drug-Distributors UDD).
    i. E-mail vaccines@udd.ie
    ii. Fax number (01) 4637788

3. The order form is available at http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gporderf.pdf
4.
5. UDD send a confirmatory email/fax outlining that they have received the order and confirming the vaccine delivery date. If this email/ fax is not received UDD should be contacted directly.

6. Vaccines should be ordered by a specific date each month as per a prescribed schedule from the HSE National Cold Chain Service.

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 HSE National Cold Chain Service 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 should 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. Any returns should be ready to hand to driver.

6.3.3. Vaccine storage, usage, stock rotation and disposal

1. Vaccines should always be stored 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.

2. Vaccine boxes should not touch the sides or back of the fridge. Air needs to circulate around the packages, therefore the fridge should not be overfilled.

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.

4. Vaccine with the shortest expiry date should be used first.

5. Once opened multi-dose vials must not be kept after the end of the session.

6. Opened vaccine vials either empty or partly used should be disposed of safely into a sharps bin and then by incineration. They should not be returned to the NCCS.

7. Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the UDD deliveryman with a completed vaccine return form. Vaccine return forms are available to download from http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hsevaccreturn.pdf

8.

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 break down 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 fridge breakdown:

1. Check the temperature on the fridge and remove the continuous temperature recording device (data logger) to download the readings and return to fridge. If there is not a data logger yet on place, read the current, maximum and minimum temperature and note the time.

2. Ensure that the fridge door is closed and fridge is working. If the fridge is not working or holding temperature between +2°C and +8°C then move vaccines to a working fridge immediately.

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 date and time of breakdown, and the type quantity and batch numbers of vaccines which are in the fridge.

5. 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.

6. **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.**

7. Vaccines that cannot be used must be removed from the fridge, details on the returns form completed and returned to the National Cold Chain service on the next delivery day.

8. The vaccine returns form is available at http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hsevaccreturn.pdf

9. 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 placed in its permanent position, 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.

7.0 References

- National Immunisation Office available at http://www.immunisation.ie
- Immunisation Guidelines for Ireland available at
- http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- Vaccine order form is available at http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gporderf.pdf
- Vaccine return forms are available to download from http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hsevaccreturn.pdf
- Centers for Disease Control and Prevention – immunisation information available at http://www.cdc.gov/vaccines/
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes. http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/SOPCoolBoxes.pdf
- Guidelines for Staff: Schools Immunisation Programme 2014/2015 available at http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/hpv/schoolguidelines.pdf
- New Zealand, Ministry of Health immunisation website available at http://www.health.govt.nz/your-health/healthy-living/immunisation
- Department of Health UK Green Book available at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

8.0 Appendices

Appendix 1: Temperature Recording Record

Health Centre	**Refrigerator location**
Month / Year	**Appliance number**

Date	Time Am /pm	Current temp (+2°C to +8°C)	Minimum temp (+2°C to +8°C)	Maximum temp (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max/min. thermometer memory cleared and checked (initial)	Signature

RECORDINGS FOR MONTH REVIEWED: **Date:** **Signature:**

Appendix 2: Stock Record

Vaccine:

Date	Batch Number	Expiry date	Trade Name	Number of doses in stock	Number of doses used	Number of doses expired/ unusable	Number of doses ordered/ received	**Signature**