



## 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 as outlined in this document.

## 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 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 (named responsible person) and the deputy staff who covers in their absence - a minimum of two people.

## 4.0 Legislation/other related policies

- i. Vaccines are prescription-only medicines (POMs) and to maintain their licensed usage should be stored and transported in accordance with the manufacturer instructions (PIL/SPC) ,in compliance with the cold chain, i.e. between  $+2^{\circ}$ C and  $+8^{\circ}$ C.
- ii. 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:\_ <u>http://www.hpra.ie/docs/default-source/publications-forms/guidancedocuments/ia-g0011-guide-to-control-and-monitoring-of-storage-andtransportation-conditions-v1.pdf?sfvrsn=4 [Accessed 24th July 2024].</u>
- iii. Guidelines and documents from other jurisdictions refer toNational Immunisation Office NIO-01Version 5 Aug2024Page 3 of 25





"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 <u>www.immunisation.ie</u>.
- ii. National Immunisation office (NIO) emails, newsletter and social media account.
- iii. National Cold Chain Services (NCCS) emails.

## 8.0 Training

An e-learning training module to update and train staff involved in handling vaccine is available on HSELanD on <a href="https://www.hseland.ie/dash/Account/Login">https://www.hseland.ie/dash/Account/Login</a> .

#### 9.0 Monitoring, Audit and Evaluation

The sites involved in a cold chain failure may be selected randomly and audited using the sample audit tool (Appendix III) to evaluate guidelines.

#### **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 product. For





vaccines the recommended temperature-controlled range is between a minimum of  $+2^{\circ}$ Celsius and a maximum of  $+8^{\circ}$ Celsius ( $+2^{\circ}$ C to  $+8^{\circ}$ C).

NCCS: National Cold Chain Service.

**NIO:** National Immunisation Office.

**USE BEFORE date:** Certain vaccine boxes are labelled by the NCCS with USE BEFORE date and time label. The USE BEFORE date and time specified on the label indicates the time by which an unopened vaccine vial can be stored at +2 °C to +8 °C and must be used irrespective of the expiry date on box or vial.

**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 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.

#### 11.2 Responsibility

The SOPs should allocate overall responsibility for cold chain management to a designated staff member (see Appendix IV). However, each vaccinator is responsible for ensuring that the vaccines they administer have been correctly stored and are in date. The cold chain 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  $+2^{\circ}C$  and  $+8^{\circ}C$ . Vaccine storage outside this temperature range or **exposed to either UV or fluorescent light** can result in the loss of potency (see Appendix V).





## 12.1 Pharmaceutical Fridges

Vaccines should only be stored in **<u>PHARMACEUTICAL FRIDGES</u>** and **<u>ONLY</u>** vaccines should be stored in this fridge.

Domestic fridges should **<u>NOT</u>** be used for vaccine storage.

#### <u>Pharmaceutical fridges should have at least the following</u> <u>specifications:</u>

- i. Features either solid or glass door which is lockable.
- ii. Maintains internal air temperature between +2°C and +8°C and the temperature can be read externally.
- iii. Fully automatic defrosting.
- iv. Fan operated, forced air cooling for temperature stability.
- v. Integral controller enabling staff to set the required temperature and easily monitor and record current/minimum/maximum levels.
- vi. Both audio and visual alarm signal when temperature deviation occurs.
- vii. Large enough to hold 3 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 a minimum of 24 hours **before** it is switched on (or as recommended by manufacturer). This allows gases to reach equilibrium before power is switched on. Then record the temperature for 48 hours (or as recommended by manufacturer) prior to its use for vaccine storage to ensure it is maintaining the correct temperature.

If the vaccine fridge has been repaired - record the temperature for 48 hours (or as recommended by manufacturer) before using the fridge to store vaccines.

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

## **12.2 Vaccine Fridge Monitoring and Maintenance**

i. The fridge should be placed in an appropriately ventilated room away from any heat source and away from direct sunlight.





ii. Fridge temperatures (current, maximum and minimum) should be recorded **twice** daily, at the start and end of each day during the working week. Recording 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 must be done before any vaccine is administered. See Appendix VI for Maintenance of Cold Chain in fridge.

The maximum/minimum reading should be cleared from the fridge memory and reset after each reading. To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should all display the same temperature (i.e. current temperature).

Reset the fridge thermometer:

- at the end of a clinic
- after the fridge door has been opened on several occasions
- after the fridge has been re-stocked or cleaned
- 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.

The ambient temperature of the room in which the fridge is located should also be monitored twice daily and recorded. In the event of fridge failure, this information may be required by the NIO in order to assess the viability of the vaccines.

iii. 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. Data loggers should be set to record temperatures at 5 to 10 minute intervals.

The data logger should be downloaded and reviewed 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 the fridge thermometer (current, maximum or minimum temperature), or the fridge has alarmed, the data logger should be downloaded to confirm 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, unless the data logger is downloaded or reviewed twice daily, morning and evening.

- iv. A temperature monitoring chart should be on each vaccine fridge door (Appendix VII). 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 and indefinitely, unless data logger records are being retained.
- v. 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 be routinely locked.

**Note:** A door that is not sealed properly or left open unnecessarily can result in a temperature recording above +8°C and therefore a temperature breach.

- vi. 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.
- vii. Prevent interruptions to the electricity supply to the vaccine fridge. This can be achieved by engaging an electrician to directly wire the fridge to the electricity supply without using a plug and using a dedicated circuit for the fridge and labelling 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 can be requested from the NIO by emailing <u>immunisation@hse.ie</u>.
- viii. 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 using a 1:10 solution of sodium hypochlorite (Milton).Vaccines should be stored in another fridge while doing this. Dry thoroughly and only restock once the temperature is within the recommended range.

- ix. 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.
- x. The fridge should be serviced and thermometers calibrated annually.
- xi. Records of servicing and cleaning should be maintained.
- xii. Vaccine storage procedures should be audited at least annually, or more frequently if experiencing cold chain problems (Please see sample Audit Tool Appendix III).
- xiii. Ensure that **adequate insurance for vaccines is in place**, to allow for vaccine replacement in case of fridge breakdown or power outages.

#### **REMEMBER THE 7Rs**

- **Read:** temperature twice daily at clinic/surgery opening and closing times.
- **Record:** maximum, minimum and current temperatures stating date and time of reading and sign/initial (Appendix VII), and download data logger regularly.
- **Reset:** after recording temperatures all 3 readings (maximum/minimum /current) should concur.
- **React:** if the temperature falls outside +2°C to +8°C and document this action (Appendix VIII & IX).
- **Review:** temperature records regularly (at least once a month).
- **Rotate:** vaccines after each delivery placing shorter dated vaccines to the front.
- **Remove:** expired stock from fridge immediately and return to NCCS for destruction.





## 12.3 Vaccine Stock Management

## 12.3.1 Vaccine ordering

- a) There should be a designated person in charge of vaccine ordering, along with a deputy to operate in their absence. 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 is required, according to the size of the target population, planned appointments and clinics and their average usage.
- b) A "vaccine stock sheet" (Appendix X) should be kept to record the date and stock on hand, stock used and quantity ordered, to facilitate prudent ordering. Online ordering is preferred as this facilitates stock recording. <u>A minimum vaccine stock of two weeks</u> supply but no more than three weeks should be kept. Overstocking can lead to wastage in the event of cold chain failure, or due to expiry date being reached which in turn could increase the risk of administering an expired vaccine.
- c) Vaccines should be ordered online or by emailing the HSE National Cold Chain Service (NCCS)
  - i. Online: <u>https://www.ordervaccine.ie/Account/Login?ReturnUrl=%2F</u>
  - ii. E-mail: <u>vaccines@udd.ie</u>
- d) The NCCS sends a confirmatory email outlining that they have received the order and confirming the vaccine delivery date. If this email is not received the NCCS should be contacted directly.
- e) Each vaccination site has an online calendar which can be viewed after logging into their account at <u>www.ordervaccines.ie</u>. This highlights the final dates for placing orders and the subsequent delivery dates. To ensure scheduled delivery, vaccines must be ordered by the cut-off time on the specific dates on the online calendar. It is good practice to print this online calendar and display it prominently for ease of reference.

## 12.3.2 Accepting vaccine deliveries

- a) Vaccine deliveries must be signed for and must be checked against the order or discrepancies. Any discrepancies or any damage must be reported to the NCCS immediately.
- b) Vaccines must be placed <u>immediately</u> in the vaccine fridge and must <u>never</u> be left at room temperature. All staff must be aware of this.





- c) Vaccines must be removed from the delivery box, checked against the delivery docket, allocated to the appropriate area in fridge and their receipt recorded.
- d) The delivery docket should be filed as it contains details of the delivery, batch number and expiry dates (or USE BEFORE dates) of products.

#### **12.3.3** Vaccine storage, usage, stock rotation and disposal

- a) 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.
- b) Vaccine boxes must not touch the sides, back or bottom of the fridge. Air needs to circulate and therefore the fridge should not be overfilled, as this will prevent proper airflow. Ideally, the fridge should never be more than two thirds full.
- c) 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 and should be used first.
- d) Once opened, multi-dose vials must not be kept after the end of the vaccination session
- e) Opened vaccine vials, either empty or partly used, should be disposed of safely into a sharps bin. They should <u>not</u> be returned to the NCCS.
- f) Expired and damaged **unopened** vaccines must not be used and should be removed from the fridge and returned to the NCCS delivery person with a completed vaccine return form. **Sharps must not be included.** A copy of the return form should be retained locally. Vaccine return forms are available to download from <u>https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vaccine-return-form-2028.pdf</u> Expired and damaged unopened vaccines <u>must not</u> be put into a sharps bin but must be returned to NCCS for destruction.





## **12.4** Procedure following breakdown in the "Cold Chain"

In accordance with the vaccine licence, all vaccines must be stored in a fridge between  $+2^{\circ}C$  and  $+8^{\circ}C$  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, e.g a delay in refrigerating vaccines once delivered, faulty fridge, electrical power cut, fridge being unplugged or switched off, or fridge door being left open.

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

- i. 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. Note the room temperature if the fridge temperature is not available.
- ii. Ensure that the fridge door is closed and fridge is working. If the fridge is not working or not holding temperature between  $+2^{\circ}C$  and  $+8^{\circ}C$  then move the vaccines to a working fridge immediately, if another fridge is available.

Determine how long the fridge has been outside temperatures between  $+2^{\circ}C$  and  $+8^{\circ}C$  by downloading the continuous temperature recording device (data logger), or other means i.e. date and time of last valid temperature recording. Calculate the hours and minutes the temperature was outside of  $+2^{\circ}C$  and  $+8^{\circ}C$ . Please do not submit downloaded data logger data to the NIO unless requested to do so.

- iii. Record the date, time and nature of the breakdown
- Record the type, quantity and batch numbers of vaccines (Appendix IX) in each fridge affected by the incident. Check if any vaccines have been administered since the cold chain breakdown occurred.

If temperatures outside the permitted range are recorded the NIO should be contacted for further advice by e-mailing <u>pharmacynio@hse.ie</u>. (see Appendix VIII for details required to be submitted via e-mail to the NIO) **Ensure that the vaccines are quarantined between +2 °C and +8 °C. Do not use or discard the vaccines until advised by the National Immunisation Office.** 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.

v. Once advised by NIO, any vaccines that cannot be used must be <u>National Immunisation Office – NIO-01</u> Version 5 – Aug2024 Page 12 of 25





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/vaccineo rdering/gpvaccreturn.pdf





#### **References:**

- Australian Government Department of Health. National Immunisation Program (2019). National Vaccine Storage Guidelines – Strive for 5, 3rd edition. [ONLINE] Available at: <u>https://www.health.gov.au/sites/default/files/documents/2020/04/nationa</u> I-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: <u>http://www.bccdc.ca/health-professionals/education-development/immunization-courses/vaccine-storage-and-handling-course</u>. [Accessed 20 June 2024].
- Centers for Disease Control and Prevention (2024). Vaccine Storage and Handling Toolkit. [ONLINE] Available at:\_ <u>https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf</u>. [Accessed 20 June 2024].
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- 5. Ontario Ministry of Health Vaccine Storage and Handling Guidelines (2021). [ONLINE] Available at <u>https://files.ontario.ca/moh-ophs-ref-vaccine-storage-handling-guidelines-2021-en.pdf</u> : [Accessed 20 June 2024].
- Public Health Agency Canada (2022). Storage and handling of immunizing agents: Canadian Immunization Guide. [ONLINE] Available at <u>Storage and handling of</u> <u>immunizing agents: Canadian Immunization Guide - Canada.ca</u>: [Accessed 20 June 2024].
- Wellington: Ministry of Health (2017). National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2<sup>nd</sup> edition). [ONLINE] Available at: <u>https://www.health.govt.nz/system/files/documents/publications/nationalstandards-for-vaccine-storage-and-transportation-for-immunisation-providerssep19.docx [Accessed 20 June 2024].
  </u>

## **National Immunisation Office website:**

- www.immunisation.ie
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes. https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02. pdf
- HSE vaccine return form available athttps://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vaccine -return-form-2028.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	Director of Public Health	National Immunisation Office		





## Appendix III: Audit Tool - National Immunisation Office

Site ref. no :	Audit unde	ertaken by:
Date :	Grade/Titl	e:

Please tick (x) the relevant box

	Equipment/Records	Yes	No	n/a
1	Is the fridge a pharmaceutical grade fridge?			
2	Is the fridge situated in an appropriately ventilated room away from any heat source and away from direct sunlight?			
3	Is the fridge door locked?			
4	Does the digital thermometer on fridge read current, maximum and minimum temperature? (Please check)			
5	Is there a data logger (recording temperatures at intervals of 5- 10 min) present in the middle of the fridge adjacent to the vaccines?			
6	Is the vaccine fridge set to alarm at +3°C or +7°C to allow time to react before +2°C or +8°C is reached?			
7	Is the power supply to vaccine fridge protected, e.g. through direct wiring of electrical supply or difficult access to the socket (e.g. behind the fridge or physical cover) or cautionary notices on plugs and sockets e.g. "Don't unplug me".			
8	Are there records present of fridge being serviced and thermometers calibrated annually? (if applicable please check last 2 years records)			
9	Are there records of data logger calibration available (if applicable please check last 2 years records)?			
10	Are fridge temperatures (current, maximum and minimum) recorded twice daily on a temperature monitoring chart? (if applicable please check last 2 months records)			
11	Are there records of fridge maintenance/fridge cleaning?			
12.	Are there any expired vaccines in the fridge?			
13	Is there evidence of stock rotation, i.e. shorter dated vaccine to the front? (Please check dates)			
14.	Are other items besides vaccines stored in the fridge e.g. food, drink or medical samples?			





## **Appendix III: Audit Tool - National Immunisation Office (cont.)**

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

Please tick (x) the relevant box

	Responsible Person/Procedures	Yes	No	n/a
15	Are there SOPs in place for the maintenance of the cold chain in vaccine fridges and vaccine stock management?			
16	Is there a named responsible person to record temperatures (current, maximum and minimum) and receive vaccines?			
17	Is there a deputy to record temperatures (current, maximum and minimum) and receive vaccines in the absence of responsible person?			
18	Is the responsible person familiar with the HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock?			
19	Is the named responsible person/deputy aware of the follow	ing:		
A	how to store vaccines in the fridge (i.e. not touching the sides, back or bottom of the fridge?			
В	how to reset the fridge thermometer after every documented reading (to ensure that reset has been carried out correctly: maximum, minimum and current temperature should read the same temperature)?			
С	that the data logger should be downloaded and reviewed regularly (at least once every two weeks) and the electronic or printed record should be retained indefinitely?			
D	that the expiry dates of vaccines must be checked regularly (at least once a month) and expired vaccines removed?			
Е	that stock rotation is carried out to ensure shorter dated vaccines are used first ?			
F	the actions needed to be taken if the temperature falls outside +2°C to +8°C (i.e. breakdown in the "Cold Chain")?			
G	procedures for returning expired stock to National Cold Chain Services (NCCS)?			





## Appendix IV: Designated staff responsibilities

The role of the designated staff member (named responsible person) involves the maintenance of the cold chain in vaccine fridges and vaccine stock management, at all vaccine storage sites. There should be a named deputy who covers in absence of the designated staff member.

#### **Responsibilities include:**

- Ordering, receipt and storage of vaccines.
- Rotating stock to ensure vaccines with the shorter expiry dates are used first.
- Removing expired vaccine from fridge and returning to NCCS.
- Documenting vaccine inventory information and temperature logs.
- Setting up temperature monitoring devices.
- Reading and recording maximum, minimum and current temperatures twice daily.
- Reviewing and analysing temperature data monthly for any shifts in temperature trends.
- Responding to temperature excursions (out-of-range temperatures).
- Ensuring equipment for storage/transport is calibrated/serviced annually or as per manufacturer specifications.
- Ensuring all new staff members who handle or administer vaccines are trained in proper vaccine storage and handling practices.
- Review and update SOPs annually.

The responsibilities may be completed by the designated staff or delegated to an appropriate staff member (deputy). The designated person is to ensure that the delegate(s) are trained and their competency documented for the specific task(s) assigned.

**REMEMBER** – Everyone who handles vaccines is responsible for maintaining the cold chain to ensure vaccine potency and efficacy.



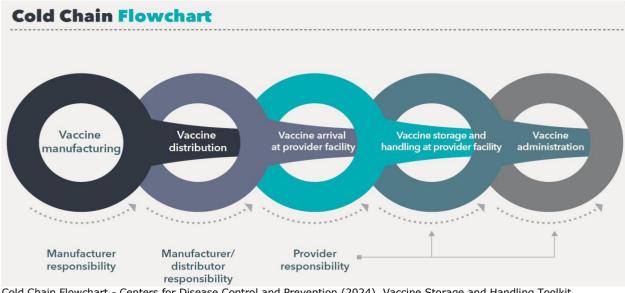


## Appendix V: Cold chain breaches and Light exposure

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

- frozen
- stored above +8°C or below +2°C
- exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light.

The **cold chain** (storage between  $+2^{\circ}C$  and  $+8^{\circ}C$ ) 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 (2024). Vaccine Storage and Handling Toolkit.

Exposure to conditions outside the parameters of  $+2^{\circ}C$  to  $+8^{\circ}C$  can affect potency of vaccines, but a single exposure to freezing temperatures ( $0^{\circ}$ 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: Maintenance of Cold Chain

#### • Temperature recording

- Record minimum, maximum and current temperature of the fridge(s) as well as the room temperature, twice daily.
- Check the fridge temperature each time before opening and retrieving a vaccine; the temperature does not need to be recorded each time.

## • Fridge

- Set fridge temperature aiming for +5°C, the midpoint in the +2°C to +8°C range.
- Set fridge to alarm at +3°C or +7°C to allow time to react before +2°C or +8°C is reached.
- Ensure that fridge is serviced and thermometer calibrated annually or as specified by the manufacturer.

**NOTE:** During a power failure, fridges may not continue to display the temperature. Fridges do not record the duration when the vaccines were exposed to temperatures outside +2°C to +8°C range, therefore use a separate independent battery-operated data logger to continuously monitor fridge temperatures during power outages.

#### • Data Logger

- Data logger should be programmed to record temperatures at intervals of every <u>5-10 minutes</u>.
- A data logger with a current and valid Certificate of Calibration testing should be used and this document should be retained indefinitely.
- Calibration of data logger should be done annually or according to the manufacturer's instructions.

## • Vaccine storage

Trays and uncovered containers (including mesh baskets and vented bins) may be used to organise vaccines in the fridge. Trays and containers should be stacked in a way that air circulation inside the fridge is not impeded. Air-tight containers or delivery boxes should not be used to store vaccines in the fridge.

**NOTE:** If ice build-up occurs, it may be an indication that there is moisture present and the fridge may not be working at full efficiency, a fridge technician should be called to assess.

**NOTE:** All vaccine temperatures recorded below +2°C or above +8°C must be reported to the NIO.





#### **Appendix VII: Temperature Log template**

	Fridg	je ID	:				M	onth					
	AM							PM					
Temperature °C		Min/Max	Timo	Initials		nperatu		Min/Max	Timo	Initiale	Comments		
Day	Min	Мах	Current	Reset	Time	Initials	Min	Max	Current	Reset	Time	miliais	Comments
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29 30													
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Monthly readings reviewed by: Date						ate :							

**Note:** When a temperature reading is missed, retain the log entry as a blank.





# Appendix VIII: Details required to be submitted to pharmacynio@hse.ie in the event of a cold chain breach

- National Cold Chain Service (NCCS) Account Number: (7 digits): 300......
- Duration (when vaccines were outside of +2 °C and +8 °C): \_\_\_hour(s)\_\_\_minutes
- Maximum (above + 8 °C) or minimum (below + 2 °C) temperature reached during this excursion: \_\_\_\_\_ °C
- Vaccine name, batch number, expiry date (or use before date in the case of COVID -19 Vaccines) and quantity involved in the temperature excursion, typed into the table below – please do not submit a handwritten form
- Were any vaccines administered since the cold chain breach happened?
- Do you have a working data logger in the fridge where the vaccines were stored?
- What was the cause of the temperature excursion?
- Since the temperature excursion, are the vaccines currently quarantined between +2 °C and +8 °C?

#### **Previous excursions**

- Were any of the vaccines involved in temperature excursions before? Yes/No
- If yes, what was the duration of exposure and temperature (max or min<sup>°</sup>C) they were exposed to: Total number of hours: **00:00** and temp: \_\_\_\_\_ <sup>°</sup>C

**Note:** If only some of the vaccines were involved in a previous temperature excursion, please identify them separately.

Vaccine Name	Batch Number	Expiry date	Quantity





manufacturer directly for advice on these products. Private vaccines adversely affected by temperature excursions must be disposed of privately.

Please do not submit downloaded data logger data to the NIO unless requested to do so.





## **Appendix X: Stock Record**

This record should be completed for each vaccine and used when any stock is moved in or out.

Fridge	Fridge ID:								
Date	Vaccine: Trade Name	Batch Number	Expiry date	Number of doses in stock	Number of doses received	Number of doses sent to site <sup>1</sup>	Number of doses returned from site <sup>2</sup>	Number of doses for destruction	Signature

1

= Number of doses sent to school/clinic/unit.

2

= Number of doses returned from school/clinic/unit still in cold chain.





# Appendix XI: Contact details – National Immunisation Office

Title/Organisation	Email
Pharmacists, National Immunisation Office	pharmacynio@hse.ie
Medical Officers, National Immunisation Office	immunisation@hse.ie