



**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 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 2 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/SmPC) in compliance with the cold chain i.e. between +2°C and +8°C.
- ii. Health Product Regulatory Authority (2017). 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 30 March 2020].
- iii. 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](http://www.immunisation.ie).
- ii. Hard copies sent to all sites that receive HSE vaccine deliveries in 2020 including GPs, pharmacies and hospitals.
- iii. National Immunisation office (NIO) emails, newsletter and twitter account.
- iv. National Cold Chain Services (NCCS) emails and twitter account.

## 8.0 Training

An e-learning training module to update and train staff involved in handling vaccine will be made 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 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 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.

**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 (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°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 V](#)).

### 12.1 Pharmaceutical Fridges

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 should have at least the following specifications:**

- 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 lasts for more than 15 minutes.
- vii. Open door sensor which alerts the user that the fridge door is not properly closed and sealed.
- viii. 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.

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

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

- 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 minutes 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 fridge thermometer (current, maximum or minimum) 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 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.

When restocking the fridge, removing vaccine, cleaning the fridge or during 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 the maximum temperature should be recorded and the memory erased. A note on the Temperature Log ([Appendix VII](#) – 'Comments' section) should indicate the cause of the increase in temperature e.g. vaccine removal. Record fridge temperature breaches and actions on the flipside of this log.

If the temperature does not return to between +2°C and +8°C within 15 minutes the National Immunisation Office (NIO) should be contacted for further advice (see [Appendix XI](#) – for contact details).

- 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 directly wiring the fridge to the electricity supply without using a plug and using a dedicated circuit for the fridge and also by labeling 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 [immunisation@hse.ie](mailto:immunisation@hse.ie).
- 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 warm slightly soapy water. 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 12 monthly 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 and all 3 readings (max/ min /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) 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 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 monthly ordering. Online ordering is preferred as this 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.
- c) 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](mailto:vaccines@udd.ie)
  - iii. Fax number:(01) 4637788
- d) The vaccine order form is available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hseorderform.pdf>
- e) The NCCS sends 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.
- f) Vaccines must be ordered by a specific date each month as per calendar available on the NCCS online ordering system to ensure scheduled delivery.

### 12.3.2 Accepting vaccine deliveries

- a) 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.
- b) Vaccines must be placed **immediately** in the vaccine fridge and must **never** be left at room temperature.
- c) The temperature on delivery should be checked and recorded to show that vaccines were in temperature on delivery.



- d) Vaccines must be removed from delivery box, checked against delivery docket, allocated to appropriate area in fridge and recorded.
- e) The delivery docket should be filed as it contains details of the delivery, batch number and expiry 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 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 session.
- e) 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.
- 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. 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 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°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”:

- 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°C and +8°C then move the vaccines to a working fridge immediately if another fridge is available.
- iii. 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 i.e. date and time of last valid temperature recording.
- iv. Record the date, time and nature of the breakdown ([Appendix VIII](#)).
- v. Record the type quantity and batch numbers of vaccines ([Appendix IX](#)) in each fridge affected by the incident.
- vi. If temperatures outside the permitted range are recorded the NIO should be contacted for further advice (see [Appendix XI](#) for contact details). 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.
- vii. Do not **use** or **dispose** of any vaccine and keep vaccines **between +2°C and +8°C in quarantine** until advised by the NIO.
- viii. Once advised by NIO, any 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>



## 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/news/the-national-vaccine-storage-guidelines-strive-for-5-3rd-edition-is-now-available> [Accessed 10 March 2020].
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 10 March 2020].
3. Centers for Disease Control and Prevention (2020). Vaccine Storage and Handling Toolkit. [ONLINE] Available at: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. [Accessed 10 March 2020].
4. NHS Greater Glasgow and Clyde (2016). Vaccine Ordering, Storage and Handling Guideline. [ONLINE] Available at: <https://www.nhsggc.org.uk/media/244993/vaccine-ordering-storage-and-handling-guideline.pdf> [Accessed 10 March 2020].
5. NHS West Hampshire Clinical Commissioning Group (2016). Cold Chain Information and Resource Pack (v1). [ONLINE] Available at: <https://westhampshireccg.nhs.uk/> [Accessed 10 March 2020].
6. 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](http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/Vaccine_Storage_and_Handling_Protocol_2018_en.pdf) [Accessed 10 March 2020].
7. 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 10 March 2020].
8. Wellington: Ministry of Health (2012). National Guidelines for Vaccine Storage and Distribution. [ONLINE] Available at: <https://www.health.govt.nz/system/files/documents/publications/vaccine-storage-guidelines-v2.pdf>. [Accessed 10 March 2020].

### **National Immunisation Office website:** [www.immunisation.ie](http://www.immunisation.ie)

- Supporting Information for Staff School Immunisation Programme 2019-2020 academic year - available at [www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff1920.pdf](http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff1920.pdf)
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes. <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf>
- Immunisation Guidelines for Ireland - available at [www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html](http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html)
- HSE vaccine order form - available at [www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hseorderform.pdf](http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/hseorderform.pdf)
- HSE vaccine return form - available at [www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvacreturn.pdf](http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvacreturn.pdf)



## APPENDICES



## Appendix I: Membership of Development Group

Name	Title	Organisation
Cliona Kiersey	Chief Pharmacist	National Immunisation Office
Achal Gupta	Chief II Pharmacist	National Immunisation Office

## Appendix II: Membership of Governance Group

Name	Title	Organisation
Dr Lucy Jessop	Director of Public Health	National Immunisation Office
Dr Chantal Migone	Specialist in Public Health Medicine	National Immunisation Office



### Appendix III: Audit Tool - National Immunisation Office

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

Please tick (x) the relevant box

	<b>Equipment/Records</b>	<b>Yes</b>	<b>No</b>	<b>n/a</b>
<b>1</b>	Is the fridge a pharmaceutical standard fridge?			
<b>2</b>	Is the fridge situated in an appropriately ventilated room away from any heat source and away from direct sunlight?			
<b>3</b>	Is the fridge door locked?			
<b>4</b>	Does the digital thermometer on fridge read current, maximum and minimum temperature? (Please check)			
<b>5</b>	Is there a data logger (recording temperatures at intervals of 5-10 min) present in the middle of the fridge adjacent to the vaccines?			
<b>6</b>	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?			
<b>7</b>	Is the power supply to vaccine fridge protected for 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".			
<b>8</b>	Are there records present of fridge being serviced and thermometers calibrated annually? (if applicable please check last 2 year records)			
<b>9</b>	Are there records of data logger being calibrated available (if applicable please check last 2 year records)?			
<b>10</b>	Are fridge temperatures (current, maximum and minimum) recorded twice daily on a temperature monitoring chart? (if applicable please check last 2 months records)			
<b>11</b>	Are there records of fridge maintenance/fridge cleaning?			
<b>12.</b>	Are there any expired vaccines in the fridge?			
<b>13</b>	Is there evidence of stock rotation i.e. shorter dated vaccine to the front? (Please check dates)			
<b>14.</b>	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

	<b>Responsible Person/Procedures</b>	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 temperature (min/max) and receive vaccines?			
17	Is there a deputy to record temperature (min/max) 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	<b>Is the named responsible person/deputy aware of the following:</b>			
A	how to store vaccines in the fridge (i.e. not touching the sides, back or bottom of the fridge ?			
B	how to reset the fridge thermometer after every documented reading ( <i>to ensure that reset has been carried out correctly: maximum, minimum and current temperature should read the same temperature</i> )?			
C	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?			
E	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 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 yearly 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 (deputy). The designated person to ensure that delegate(s) are trained and their competency documented for the specific task(s) assigned.

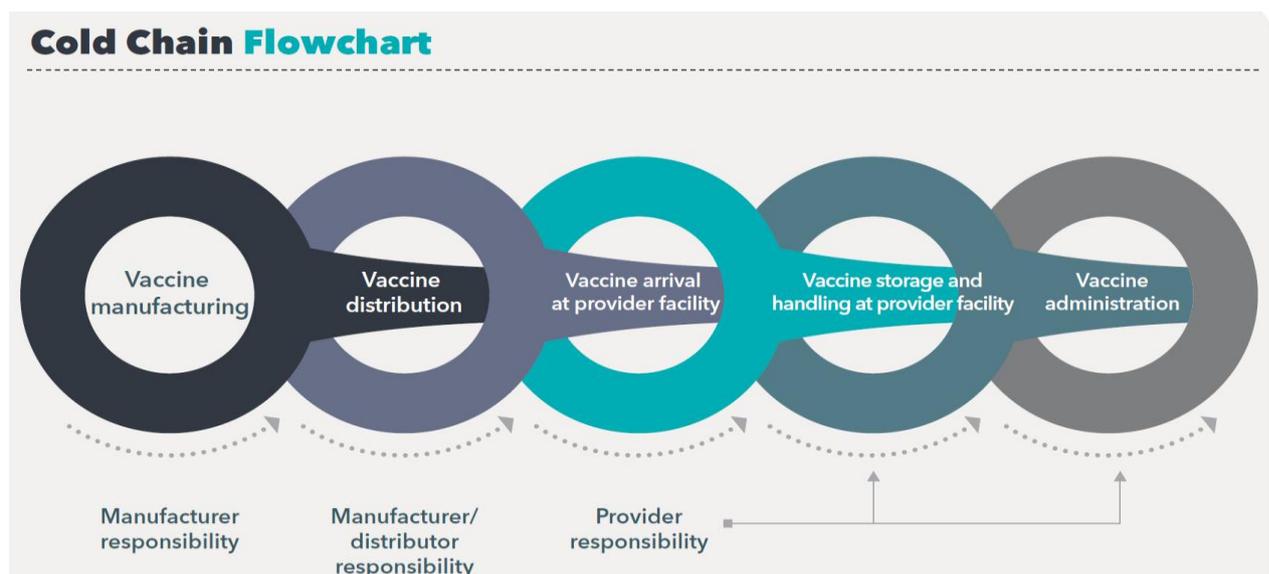
**REMEMBER** – Everyone who handles vaccines is responsible for maintaining the cold chain to ensure vaccine potency and efficacy.

## 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
- 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: 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 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 at least every 5-10 minutes.
- Only data logger with a current and valid Certificate of Calibration testing should be used and retain indefinitely this document.
- 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 vaccine 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. This does not include temperature deviations or excursions above +8°C for 15 minutes or less. Any deviation below +2°C must be reported.



### Appendix VII: Temperature Log template

<b>Fridge ID:</b>	<b>Month :</b>
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Day	AM						PM						Comments
	Temperature °C			Min/Max Reset	Time	Initials	Temperature °C			Min/Max Reset	Time	Initials	
	Min	Max	Current				Min	Max	Current				
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													
24													
25													
26													
27													
28													
29													
30													
31													

<b>Monthly readings reviewed by:</b>		<b>Date :</b>	
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**Note:** When a temperature reading is missed, retain the log entry as a blank.



## Appendix VIII: Report following breakdown in Cold Chain

(Please fill this form separately for each fridge and email to the immunisation@hse.ie)

<b>Name of Site</b>		<b>Phone</b>	
<b>Account no.</b>	300.....	<b>Email</b>	
<b>Contact person</b>		<b>Mobile</b>	

<b>Date and time "Cold Chain" breach occurred (noticed)</b>			
Date (DD/MM/YYYY):		Time (use 24 h clock):	
<b>FRIDGE temperature at time of breach in "Cold Chain" identification</b>			
Fridge ID	Current (°C)	Minimum (°C)	Maximum (°C)
<b>Description of incident:</b>			

### Last recorded temperature of fridge and reset

Fridge ID	Date last record (DD/MM/YYYY):	Time last record (use 24 h clock):	Date last reset (DD/MM/YYYY):	Time last reset (use 24 h clock):

### Current Fridge temperature at present (if vaccines moved to another fridge -indicate by recording in the Fridge ID\*)

Fridge ID*	Date (DD/MM/YYYY):	Time (use 24 h clock):	Current (°C)	Minimum (°C)	Maximum(°C)

### DATA LOGGER details

Fridge ID	Time when reading exceeded +8°C or dropped below +2°C (use 24 h clock):	Time when reading became normal i.e. between +2°C and 8°C (use 24 h clock):	<b>Duration</b> (when fridge outside of +2 and + 8 °C) - (use 24 h clock):
			___ hour ___ min

### ROOM TEMPERATURE (where fridge is located)

Minimum room temperature during the excursion period (°C)	Maximum room temperature during the excursion period (°C)

- Note:**
1. Please do not use or dispose of any vaccines unless advised by the NIO.
  2. Quarantine all vaccines within cold chain conditions and notify relevant staff.
  3. Temperature excursions are cumulative and if some of the vaccines were exposed to previous breaches please specify and give details.
  4. HSE sites only - please fill the National Incident Report Form (NIRF-04 Complaint/Dangerous occurrence).



## Appendix IX: Vaccines involved in “Cold Chain” breakdown

Fridge ID: VACCINE	TRADE NAME	BATCH NUMBER	EXPIRY DATE	QUANTITY	Please specify duration - <i>If any vaccines were involved in previous temp. excursions</i>
<b>School Immunisation Programme</b>					
DTaP/IPV (4in1)					
HPV					
Men ACWY					
MMR					
Tdap					
Tdap /IPV(4in1-low dose)					
<b>Primary Immunisation Programme</b>					
DTaP/IPV/HIB/HepB (6in1)					
Hib/MenC					
MenB					
MenC					
MMR					
PCV13					
Rotavirus					
<b>Seasonal</b>					
Influenza Vaccine					
PPV23					
<b>Others</b>					
Hepatitis A Adult					
Hepatitis A and B Adult					
Hepatitis A Paediatric					
Hepatitis B Adult					
Hepatitis B Paediatric					
Hepatitis B Renal (higher dose)					
MenACWY					
Td					
Tdap					

**NB:** The NIO cannot comment on the temperature stability of any vaccines purchased privately- contact the manufacturer directly for advice about any private vaccines involved in the incident.



## Appendix X: Stock Record

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

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	Phone/Mobile	Email
Pharmacists, National Immunisation Office	087 9915452	<a href="mailto:Cliona.kiersey@hse.ie">Cliona.kiersey@hse.ie</a>
	087 4064810	<a href="mailto:Achal.gupta@hse.ie">Achal.gupta@hse.ie</a>
Medical Officers, National Immunisation Office	01 8676108	<a href="mailto:Immunisation@hse.ie">Immunisation@hse.ie</a>