Family Nursing & Home Care

Vaccine Cold Chain Policy and Procedures

4 August 2021

Document Profile

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Title	Vaccine Cold Chain Policy and Procedures
Author	Mo de Gruchy in consultation with Senior School Nurse
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Version control / changes made

Date	Version	Summary of changes made	Author
June 2021	1	Previous policy transferred onto new template Content reviewed and updated in line with latest evidence and guidance from UK Department of Health, Public Health England and Jersey Health & Community Services	Mo de Gruchy

CONTENTS

1. INTRODUCTION

1.1 Rationale

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of +2˚C to +8˚C until the point of administration.

Vaccines may lose their effectiveness if they become too hot or too cold at any time. Vaccines naturally biodegrade over time, and storage outside of the recommended temperature range – including during transport – may speed up loss of potency, which cannot be reversed. This may result in the failure of the vaccine to create the desired immune response and consequently provide poor protection. Inappropriate storage and transport also results in wastage and unnecessary costs to the health service.

Immunisation providers need to know how to purchase, replace, maintain or upgrade their existing cold chain equipment for storing and transporting vaccines in their immunisation setting.

The essential cold chain equipment needed to transport and store vaccines within a consistent safe temperature range include:

- A pharmaceutical fridge for storing vaccines
- A digital or electronic minimum/maximum thermometer and chart for recording daily temperature readings
- Validated cool-boxes for transporting vaccines or for temporary storage (such as when immunising at outlying clinics/surgeries)
- Cool packs to keep vaccines cool (but not in danger of freezing) during transportation/temporary storage
- Material to separate cool packs from the vaccines when use of frozen cool packs in indicated (such as within the Mini-Porter®).

This policy gives clarity and guidance to Family Nursing & Home Care (FNHC) staff involved in monitoring and maintaining the cold chain. It aims to ensure that vaccines are received, stored and managed properly so that immunisations are carried out safely and efficiently.

1.2 Scope

This policy applies to any FNHC staff who are involved in the handling and storage of refrigerated vaccines. It does not necessarily apply to all vaccines e.g. COVID-19 vaccines, as these will have separate vaccine-specific requirements.

1.3 Role and Responsibilities

Chief Executive Officer

The Chief Executive Officer has ultimate responsibility for ensuring that FNHC has robust governance measures in place to support the safe handling and management of vaccines.

Head of Quality Governance and Care

The Head of Quality Governance and Care is responsible for ensuring that FNHC has evidence based procedural documents available to ensure the safe handling and management of vaccines is followed and that these are reviewed at appropriate intervals. They are also responsible for monitoring any incidents relating to this practice and the implementation of any action required to prevent reoccurrence of untoward incidents.

Operational Leads

Operational leads are responsible for ensuring that their teams have access to this policy and for overseeing the monitoring of staff competence and attendance at any training. They also have a responsibility to ensure that any untoward incidents are investigated and action taken as necessary to mitigate risk.

All staff

All FNHC staff involved in vaccine handling and management from point of receipt to administration have a responsibility to adhere to this policy and to report any untoward events related to this practice.

Designated Practitioner

FNHC will identify a designated practitioner (and a deputy) who will be responsible for receiving vaccine supplies and monitoring their storage.

2. POLICY

2.1 Ordering vaccines

In Jersey the Department of Health and Community Services (HCS) has responsibility and oversees all vaccine transportation from the UK to the island and must ensure that processes are in place to maintain a Cold Chain to the point of FNHC's receipt of any vaccines.

Vaccine stocks should be monitored regularly to avoid shortages, under or over-ordering or stockpiling

Best practice is to order small quantities on a regular, scheduled basis. Ordering should be undertaken in sufficient time to ensure that there is always an adequate supply for planned clinics and scheduled appointments (e.g. travel vaccines or booster doses).

2.2 Receipt of vaccines

A designated practitioner (and a deputy) should be responsible for receipt of vaccines. Reception staff must be aware of the importance of ensuring vaccines are handed over to the person responsible for them as soon as possible and must know what action to take if either the person or their deputy is unavailable.

Vaccines should be checked for damage before signing for them.

If the person receiving the vaccine delivery is not assured that the cold chain has been maintained, they should refuse to accept the order and return it to the supplier.

Vaccines should be refrigerated immediately on receipt and not left at room temperature.

Vaccine names, batch numbers and expiry dates should be checked against what is recorded on the delivery note. The member of staff accepting delivery must date and time the delivery note to show when stock was received. Delivery notes should then be retained according to FNHC Records Retention Policy.

2.3 Storage of vaccines

2.3.1 Refrigerators

Specialist refrigerators are available for the storage of pharmaceutical products and must be used for vaccines and diluents. Ordinary domestic refrigerators must not be used.

Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines.

Opening of the refrigerator door should be kept to a minimum in order to maintain a constant temperature. The fridge temperature gauge should be clearly visible to read without needing to open the fridge door.

As a minimum for providing adequate refrigerator conditions, the named individuals should ensure that:

- all fridges have a unique identifier, such as a serial number
- the refrigerator is safe, for example by undertaking regular visual inspections and Portable Appliance Testing (PAT).

- the refrigerator is lockable or within a locked room. All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions.

- the refrigerator is the right size to meet the vaccination storage needs, i.e. there is sufficient space around the vaccine packages for air to circulate and there is sufficient capacity for vaccines for seasonal/ additional programmes such as the annual influenza vaccination campaign

- the refrigerator is placed in a suitable position (ventilated and away from heat sources)

- the refrigerator is maintained in a clean condition

- ice is not building up in the fridge. If defrosting is necessary, vaccines should be stored temporarily in a suitable alternative refrigerator or in a validated medical-grade cool box, but for the minimum possible time

- there is a maintenance contract that allows for at least yearly servicing and calibration of the temperature gauge

- steps have been taken to reduce the probability of accidental interruption of electricity supply, such as installing a switchless socket or clearly labelling the vaccine refrigerator plug.

Records should be kept of regular servicing, defrosting and cleaning, calibration and electrical testing. All maintenance actions should be recorded on a log sheet.

2.3.2 Thermometers and temperature readings

Modern medical/pharmaceutical fridges have a built in thermometer which displays the fridge temperature on the outside of the door. These appliances also have an alarm which is activated if the temperature exceeds 8°C or falls below 2°C

All fridges should ideally have two thermometers, one of which is a maximum/minimum thermometer independent of mains power

Care should be taken that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range.

Temperatures in the fridge are to be monitored and recorded at least once each working day, preferably twice a day, and documented as maximum reading, minimum reading and actual reading.

The maximum and minimum functions must be reset after each temperature reading using the appropriate chart (Appendix 1).

The monitoring of fridges is often referred to as observing the four Rs:

- **Read** - at the same time every day during the working week and signs the sheet
- **Record** - in a standard fashion and on a standard form
- **Reset** - resets the thermometer after each reading.
- **React** - if the temperature falls outside +2ºC to +8ºC

Electronic Temperature Data Loggers may also be used in addition to min/max temperature monitoring. The loggers are similar in size to a small matchbox; they are free standing and should be placed on a middle shelf within the body of the fridge. A logger can be set to read the internal fridge temperature at pre-determined intervals e.g. at 15 minute intervals.

When a readout of the fridge temperature data is required (e.g. once weekly), the logger is connected to a PC via a USB port and specialist software enables the temperature data on the logger to be downloaded to a PC file, these temperatures can then be printed out and used for precise checking of the vaccine temperatures.

Loggers are extremely useful when large amounts of vaccines are being stored or when very detailed temperature records are required in addition to the minimum/maximum temperature display.

2.3.3 Organisation of stock within refrigerator

Best practice must ensure that:

- The fridge is not overstocked (NB fridge should not be stocked more than 50% full)

- Nothing must touch the back or sides of the fridge (this could result in frozen vaccines)

- Vented boxes or wire baskets can be used to store vaccines within the fridge to help keep vaccine brands together and prevent any loose vaccines falling to the back of the fridge. If vented boxes/wire baskets are used then they should be loosely packed within the box/basket to allow for ample air circulation around the vaccines/prevent crushing damage

- Certain shelves can be designated for different vaccines – this should be listed on the outside of the fridge to minimise the length of time the door is kept open when searching for a vaccine

- Vaccines should be removed from all delivery packaging and stored as individual units (in the manufacturer's original packaging) and not kept in cardboard boxes or plastic bags

- Stock should be properly rotated by the designated person (i.e. stock with the longest expiry date is put at the back so the stock with the shortest expiry date is always used first)

- Vaccines should be stored in the manufacturer's original packaging – many are sensitive to light and thus will deteriorate if taken out of boxes

- Any short dated stock should be clearly labelled and used first

- Any out-of-date stock should be clearly labelled, removed from the refrigerator immediately and disposed of as per FNHC Waste Management Policy

- Damaged vaccines – Where the vial or syringe containing the vaccine, diluent or the immunoglobulin is damaged or not intact, the vaccine should not be used. These should be removed from use immediately, labelled as damaged and either disposed of as per FNHC Waste Management Policy or reported as a product defect.

2.3.4 Storage of reconstituted vaccines

For some vaccines, there is a need to reconstitute the vaccine using a diluent.

Storage requirements for the reconstituted vaccines vary and the Summary of Product Characteristics (SPC) or packaging insert should be consulted to identify the specific requirements for these vaccines.

Generally, it is not good practice to reconstitute vaccines in advance, although in some cases, such as using multi-dose vials, it can be considered.

If a vaccine is reconstituted but not used immediately, it is good practice to label the vaccine with date and time of reconstitution and the initials of the person reconstituting the vaccine.

These reconstituted vaccines should be stored in line with the guidance given in the SPC or packaging insert and any local policies.

2.4 Stock control

The nominated persons are responsible for ensuring there is good stock management and monitoring of stock. The system should:

- keep track of orders
- keep track of expiry dates, and
- keep a running total of vaccines, including wastage

The systems should be updated immediately upon ordering and receipt of vaccines and at the end of clinical sessions where vaccines have been administered.

2.5 Incidents

All deviations from this policy or the cold chain must be reported to a designated manager. The incident must be reported according to the local incident reporting policy.

2.6 Training requirements

Any person involved in the maintenance of the cold chain must be suitably trained. Cold chain compliance must be incorporated into immunisation and vaccination training.

3. PROCEDURES

3.1 Ordering and receipt of vaccines

- A childhood vaccine order can be placed weekly
- Complete the order form and email it to the Pharmacy Department at the General Hospital. The vaccine order form must be signed by a designated authorised signatory i.e. registered practitioner
- The vaccine order form must reach the Pharmacy Department by 12.30 hours on Tuesday (that is by the Tuesday prior to the Friday when delivery will be made)
- Influenza vaccines for the annual staff influenza campaign are ordered in writing from the Pharmacy Department at the General Hospital. See SOP Staff Influenza Immunisation Programme (currently under development).
- Vaccines should be ordered frequently and in small quantities (that is, do not store more stock than is needed)
- Responsibility for this must be allocated to a designated practitioner (appoint a named deputy for holidays, sickness etc.)
- Delivery of vaccine will be in a VaccinePorter® cool box, clearly labelled. The delivery driver will require a signature from the person receiving the order. A copy (blue sheet) should be retained for FNHC records
- Delivered vaccines must be unpacked as soon as they arrive and promptly stored in the vaccine fridge. Deliveries should be inspected for leakages and damage and the Pharmacy Department contacted if any products are affected.
- Goods received should be checked against the order and any discrepancies reported to the Pharmacy Department as soon as possible

- Place vaccines with longest expiry dates to the back shelves; operate a stock rotation system using oldest stock first (note that if the vaccine expiry date shows only the month and year, the vaccine may be used up until the last day of the month)

- Consideration needs to be given when special activities arise that impact on vaccine supplies (e.g. a local immunisation catch-up campaign or immunisation promotion programme)

- The vaccine stock sheet must be completed

3.2 Storage of vaccines

- A designated person should monitor and record the minimum/maximum temperatures of the vaccine fridge daily (or twice daily) using the appropriate chart (appendix 1) and the thermometers should be reset following each monitoring

- There should be a planned emergency storage procedure should the vaccine fridge fail

- Vaccines MUST NOT be used if they have been frozen

- Items other than medicines e.g. food and drink, MUST NOT be stored in the vaccine refrigerator

- Vaccines should not be too tightly packed within the fridge. There should be adequate room for cold air to circulate

- Vaccines should be stored in the fridge within their original packaging regardless of their bulkiness (that is keep vaccine vials within the product box provided by the manufacturer) as this protects the vaccine from light

- Stocks should be stored tidily. Vaccines should not be stored within shelves or compartments of the fridge door

- There should be established stock rotation – put new stock to the rear and bring existing stock forward

3.3 Transporting vaccines

- Domestic cool boxes **must not** be used to store, distribute or transport vaccines

- Validated cool boxes e.g. VaccinePorter® and cool packs from a recognised medical supply company should be used in conjunction with validated maximum–minimum thermometers. A data logger is required if vaccine is to be transported and then subsequently returned to the base refrigerator

- Cool packs should be stored in accordance with the manufacturer's instructions, usually at +2˚C to +8˚C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature

- In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit. The exception to this is when the cool box manufacturer's instructions specifically state that ice packs should be used

- Individual manufacturer's instructions must be strictly adhered to

- A validated cool box provides ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport

- With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods, so monitoring is always required

- The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours

- Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box with cool packs as per the manufacturer's instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage

- When transporting vaccines, named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the vaccine refrigerator. These should be placed quickly into the validated cool boxes and opening must be kept to a minimum

3.4 Vaccine handling

- Vaccines should only be removed from the base fridge at the beginning of the session when they will be used. They should be returned to the base fridge immediately after the session

- All vaccines required for a session should be removed from the fridge at the same time to avoid frequent opening and closing of the fridge door

- The vaccine log must be completed at least monthly and also when vaccines are removed from the fridge or when the surplus is returned, or both.

- Vaccines should be out of the fridge for as short a time as possible, no longer than three hours, therefore, only the required number of doses should be taken

- There is NO necessity to warm vaccines prior to use

- The identity of the vaccine should be checked and also its colour and clarity
- A check and note should be made of the vaccine expiry date prior to use
- Once opened, multi-dose vials must be disposed of at the end of the vaccine session or, if the manufacturer's recommended period has expired, whichever is soonest
- If vaccines have been kept out of the fridge/validated cool box for short periods but were not used (for example, if they were kept on the work bench during a vaccination clinic session) they should be clearly labelled using a "red dot" label and used on the next vaccination opportunity
- If the vaccine is taken out of the cold chain a second time but not used, it should be discarded (see section regarding Disposal of Vaccines)

3.4 Returned vaccines that have been transported

- Vaccination sessions away from the base clinic should be planned in such a way that the correct amount of vaccine is transported, thereby minimising any need to return vaccine
- In general, unused vaccines may be returned to the base clinic vaccine refrigerator, providing there is evidence from the data logger that the cold chain has been maintained
- Returned vaccines should be marked, segregated and used at the earliest opportunity
- This general information is not applicable to all situations and vaccine specific information should be followed where this is available, for example vaccines that are particularly temperature sensitive or require complex handling
- If the cold chain cannot be guaranteed, then advice must be sought from the Pharmacy Department and if necessary, the vaccines should be destroyed

3.5 Disposal of vaccines

- All reconstituted vaccines and opened single and multi-dose vials must be used within the period recommended by the manufacturer
- Intact and unopened fridge items which are no longer required (e.g. out-of-date stock) must be disposed of in an appropriate coloured sharps bin for incineration
- At the end of an immunisation session any remaining reconstituted vaccine must be disposed of in an appropriate coloured sharps bin for incineration

- Use yellow-lidded sharps bin for all vaccines, except for BCG vaccine which must be disposed of in a purple-lidded sharps bin as it is classed as cytotoxic/cytostatic (as per FNHC Waste Management Policy)

3.6 Spillages and breakages

- Spillages on skin should be washed with soap and water. If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought

- When clearing up spillages and breakages refer to any safety data sheets supplied with the product for guidance. Spillages must be cleared up quickly and gloves should be worn. Spillage kits should be used, if available. The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles

- The area should be cleaned and gloves, towels, etc. should be disposed of according to FNHC Waste Management Policy.

3.7 Action in the event of Power Failure

- During a power failure of four hours or less, the vaccine fridge door should be kept closed

- If the power failure continues for more than four hours, consider the possibility of transferring the vaccines to another clinic site with power

- Alternatively the vaccines should be moved to a validated cool-box/insulated container with cool packs (if power failures are a common occurrence consider purchasing a back-up generator)

3.8 Action in the event of Cold Chain Failure

If there is evidence or a suspicion that vaccine has been exposed to temperatures outside the recommended 2-8□C range:

- Immediately 'seal' the vaccine fridge to ensure that vaccines cannot be used (i.e., tape the fridge or place notices on the fridge indicating that vaccines cannot be used at the present time) and make all users aware. **Do not dispose of the vaccine.**

- Establish the exact period of temperature deviation (if a data logger system is used, download the recent fridge readings or use paper records of min/max temperatures).

- Compile a list of which immunisations (if any) have been given and to whom during the period of cold chain failure.

- Contact the HCS Immunisation Nurse Specialist for advice
- Complete both pages of the Cold Chain Incident Report form (Appendix 2) and scan/email to Immunisation Nurse Specialist
- If the Immunisation Nurse Specialist is not available or on leave, they will make contact with you on their return (from leave). **Do not dispose of the vaccine.**
- Report details of the incident on the Assure reporting system.
- Note that, if the cold chain cannot be guaranteed for vaccines that have been administered to patients, it is likely that those patients will need to be recalled to receive repeat vaccinations.
- Inform the person designated to be in charge of all the refrigerators or a manager, in their absence, so that a repair engineer can be called.

4. CONSULTATION PROCESS

Name	Title	Date
Judy Foglia	Director of Governance Regulation and Care	08/07/2021
Michelle Cumming	Operational Lead Child and Family Services	08/07/2021
Tia Hall	Operational Lead Adult Nursing Services	08/07/2021
Jo Davies	Senior School Nurse	08/06/2021 08/07/2021
Marion Lee	Immunisation Nurse Specialist HCS	29/06/2021
Deborah O'Driscoll	Pharmacy Services Manager HCS	06/07/2021
Elspeth Snowie	Clinical Effectiveness Facilitator	08/07/2021

5. IMPLEMENTATION PLAN

Action	Responsible Person	Planned timeline
Email to all staff	Secretary/Administration Assistant (Quality and Governance Team)	
Policy to be placed on organisation's Procedural Document Library	Secretary/Administration Assistant (Quality and Governance Team)	

Forms/templates to be uploaded to Central Filing	Head of Information Governance and Systems	

6. MONITORING COMPLIANCE

Compliance with this policy will be monitored by audit of relevant documentation and following up of any related incidents where these have been reported on the Assure system.

To reduce the risk of cold chain incidents, it is important for cold chain procedures to be audited regularly. An audit tool is included as Appendix 3 to this document to enable 'self-assessment' of cold chain arrangements. This tool also provides an indication of the best practice criteria that would be examined during a cold chain audit.

7. EQUALITY IMPACT STATEMENT

Family Nursing & Home Care is committed to ensuring that, as far as is reasonably practicable, the way services are provided to the public and the way staff are treated reflects their individual needs and does not discriminate against individuals or groups on any grounds.

This policy document forms part of a commitment to create a positive culture of respect for all individuals including staff, patients, their families and carers as well as community partners. The intention is to identify, remove or minimise discriminatory practice in the areas of race, disability, gender, sexual orientation, age and 'religion, belief, faith and spirituality' as well as to promote positive practice and value the diversity of all individuals and communities.

The Family Nursing & Home Care values underpin everything done in the name of the organisation. They are manifest in the behaviours employees display. The organisation is committed to promoting a culture founded on these values.

Always:

- ✓ Putting patients first
- ✓ Keeping people safe
- ✓ Have courage and commitment to do the right thing
- ✓ Be accountable, take responsibility and own your actions
- ✓ Listen actively
- ✓ Check for understanding when you communicate
- ✓ Be respectful and treat people with dignity
- ✓ Work as a team

This policy should be read and implemented with the Organisational Values in mind at all times.

8. GLOSSARY OF TERMS

Cold Chain – A cold chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range.

Designated Practitioner – A practitioner who performs a specific function relating to the use of medicines. The appointed practitioner in charge must check that they are competent. Designated practitioners can include medical practitioners, midwives, nurses, pharmacists, pharmacy technicians, residential childcare officers, chiropodists, dentists, operating department practitioners, orthoptists, physiotherapists, radiographers and health care assistants (GofJ 2018)

Immunisation – the act of making immune (especially by inoculation)

Inoculation - The introduction of an antigenic substance or vaccine into the body to produce immunity to a specific disease.

Vaccination – Any inoculation intended to raise immunity to a disease

9. REFERENCES

Government of Jersey (2018) *Medicines Policy.* Health & Community Services, Jersey

Government of Jersey (2020) *Vaccine Cold Chain Policy 5th edition.* Health & Community Services, Jersey

Public Health England (2014) *Protocol for ordering, storing and handling vaccines.* Available at: Protocol for ordering storing and handling vaccines (publishing.service.gov.uk). Last accessed 4th June 2021

Public Health England (2020) *Green Book Chapter 3: Storage, distribution and disposal of vaccines.* Available at: Green_Book_Chapter_3_v3_0W.pdf(publishing.service.gov.uk). Last accessed 4th June 2021

Specialist Pharmacy Service (2021) *Policy for Maintaining the Vaccine Cold Chain (Primary Care).* Available at: Example policy for Maintaining the Vaccine Cold Chain in Primary Care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. Last accessed 7th June 2021

10. APPENDIX

Appendix 1 Refrigerator Temperature Record Chart

FRIDGE .....

PLEASE RECORD MAXIMUM AND MINIMUM TEMPERATURE

VACCINE TEMPERATURE CHART

Temp °C	MONTH:																													
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
15°C																														
14°C																														
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2°C																														
1°C																														
0°C																														
- 1°C																														
- 2°C																														
CHECKED BY:																														
TIME:																														
COMMENTS																														

FRIDGE .....

PLEASE RECORD MAXIMUM AND MINIMUM TEMPERATURE

VACCINE TEMPERATURE CHART

Temp °C	MONTH:																													
	17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
15°C																														
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0°C																														
- 1°C																														
- 2°C																														
CHECKED BY:																														
TIME:																														
COMMENTS																														

Appendix 2 Cold Chain Incident Report Form

Health & Community Services

Preventive Programmes Team
Maison Le Pape, The Parade, St Helier, Jersey, JE2 3PU,
Tel: +44 (0)1534 445790, Fax: +44 (0)1534 445772 Email **m.lee@health.gov.je**

For each break in Cold Chain please report to Marion Lee, Immunisation Nurse Specialist

Once completed, please scan/email all pages of this form to m.lee@health.gov.je

- **Practice name:**

_____

- **Tel:**

_____

- **Please report the type and number of vaccines affected below:**

Vaccine	State Quantity
DTaP/IPV/Hib/HepB **Infanrix-hexa**	
Hib/MenC **Menitorix**	
Men B **Bexsero**	
MMR **Priorix**	
MMR **Vax-Pro MMR**	
Pneumococcal conjugate **Prevenar 13** (PVC)	
Rotavirus **Rotarix**	
dTaP/IPV **Repevax**	
DTaP/IPV **Infanrix-IPV**	
Influenza **Fluenz** nasal spray	
DTaP/IPV **Boostrix**	
Shingles **Zostavax**	
Other childhood vaccines:	

Date of incident: _____

Name of notifier: _____

Contact telephone: _____

Location of Cold Chain Breach/Incident:_____

Description of Incident:

<u>COLD CHAIN BREACH/INCIDENT CHECK LIST</u> Please complete as much of the following table as possible to help us assist you with rapid decision making about a suspected cold chain breach/incident.

Date of Breach	
Do you store your vaccines in a domestic or purpose built vaccine fridge?	
Minimum and maximum temperature reading?	
When was the thermometer last reset?	
When was the thermometer battery last changed (if applicable)	
When was the last check on the accuracy of the thermometer done?	
How long do you think the temperature was outside +2◦C to +8◦C?	
How long do you think these problems have been occurring?	
Where is the temperature probe situated?	
Where are the vaccines stored in the fridge?	
Have vaccines been pushed up against the cooling plate or a cold air outlet?	
Are the vaccines in their packaging?	
What do you think was the cause of the cold chain breach?	
Has the cause of the cold chain breach been rectified?	

Has anybody been vaccinated with potentially affected vaccines?	
Which fridge was affected?	
How long has the fridge been malfunctioning?	
When were the correct temperatures last recorded?	
When is the next vaccination session? Where will these vaccines come from?	

Appendix 3 Vaccine Cold Chain Audit Tool

1. GENERAL

1.1 Is a copy of the local guidelines for vaccine handling and storage available? YES / NO

1.2 Is there a named individual who is responsible for:

ordering/receiving vaccines? YES / NO

monitoring the storage of vaccines? YES / NO

Name of individual ……..

1.3 Is there a named deputy who is responsible for:

ordering/receiving vaccines? YES / NO

monitoring the storage of vaccines? YES / NO

Name of individual ……..

2. RECEIPT

2.1 Do goods received match the delivery note? YES / NO

2.2 Do goods received match the order? YES / NO

2.3 Are deliveries signed for on receipt? YES / NO

2.4 Is the order stored immediately on receipt? YES / NO

3. STORAGE

3.1 Are vaccines stored: in a medical / pharmaceutical fridge? YES / NO

3.2 Is the fridge lockable? YES / NO

3.3 Is the fridge situated near to a heat source? YES / NO

3.4 Is there enough space for air to circulate freely around back of the fridge? YES / NO

3.5 Is the fridge located in an area with restricted public access? YES / NO

3.6 Is the fridge plug secured to the wall and/or labelled? YES / NO

3.7 Are the contents evenly distributed within the fridge to allow air to circulate? YES / NO

3.8 Is the cold store / fridge dedicated to vaccines? YES / NO
If no, what else is stored? ……

3.9 Is there any out of date stock stored in the fridge? YES / NO
If Yes, is the stock clearly labelled as such? YES / NO

3.10 Is stock rotated according to expiry date? YES / NO

3.11 Is the fridge serviced on a regular basis in line with manufacturer's instructions? YES / NO

3.12 Is the fridge checked, (defrosted, if required) and cleaned on monthly basis? YES / NO If No, how often ……..……..

3.13 Is a record made of this check? YES / NO

3.14 If the fridge requires defrosting, are the vaccines kept in a cool box or alternative fridge whilst this is carried out? YES / NO
If No, where are the vaccines kept? …….

3.15 Is the temperature of the fridge recorded by a:
chart? YES / NO maximum/minimum thermometer? YES / NO data logger? YES / NO

3.16 Does the fridge have an alarm which is activated when the temperature exceeds 8 degrees C or falls below 2 degrees C? YES / NO

3.17 Are the following storage temperatures monitored and recorded each working day before any issue/administration of vaccines:

maximum temperature over last 24 hrs? YES / NO
minimum temperature over last 24 hrs? YES / NO
actual temperature at time of checking? YES / NO

3.18 Is the thermometer reset after each reading is made? YES / NO

4. TRANSPORTATION OF VACCINES

4.1 Are vaccines always transported in a cool box? YES / NO

4.2 Is this a validated cool-box? YES / NO

4.3 Are cooled fridge/freezer packs placed in the cool box? YES / NO

4.4 If freezer packs are recommended, eg, as used in Mini-porter®, are these removed from the freezer 20 minutes prior to use? YES / NO

4.5 If freezer packs are recommended, e.g., as used in Mini-porter®, is a spacer mat used?

4.6 If the cool-box is not validated, is the temperature within the cool box monitored? YES / NO If yes, state how .....……

4.7 What action is to be taken if the temperature falls outside 2 - 8 degrees C?
.....……
……..
……...

5. VACCINATION SESSION

5.1 If vaccines are to be administered away from base are they removed from the base fridge immediately before leaving for the session? YES / NO

5.2 At the end of a session away from base are the vaccines returned immediately to the base fridge? YES /NO

5.3 Is the vaccine fridge in the room where vaccines are administered? YES / NO

5.4 Are all vaccines required for the session taken from the fridge at the same time? YES / NO

5.5 Are vaccines left out of the fridge for longer than 3 hours? YES / NO

5.6 If taken to an outside clinic / patients' home are vaccines carried in suitable cool containers? YES / NO

5.7 Are unused vaccines from a clinic session coded (e.g., red dotted)? YES / NO

5.8 Are such vaccines used first next time? YES / NO

5.9 If vaccines have been removed from the cold chain twice and are still unused, are they then destroyed? YES / NO

6. MONITORING AND REPORTING INCIDENTS

6.1 Is any fridge falling outside the limits of 2 degrees C to 8 degrees C reported to the appropriate manager? YES / NO

6.2 Does the clinical area have a mechanism for recording all cold chain incidents, whatever the source? YES / NO

Appendix 4 Equality Impact Screening Tool

Stage 1 - Screening			
Title of Procedural Document: Vaccine Cold Chain Policy			
Date of Assessment	July 2021	Responsible Department	Clinical
Name of person completing assessment	Mo de Gruchy	Job Title	Quality Performance and Development Nurse

Does the policy/function affect one group less or more favourably than another on the basis of :	**Yes/No**	**Comments**
• Age	No	
• Disability Learning disability; physical disability; sensory impairment and/or mental health problems e.g. dementia	No	
• Ethnic Origin (including hard to reach groups)	No	
• Gender reassignment	No	
• Pregnancy or Maternity	No	
• Race	No	
• Sex	No	
• Religion and Belief	No	
• Sexual Orientation	No	
If the answer to all of the above questions is NO, the EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 2		

Stage 2 – Full Impact Assessment			
What is the impact	**Level of Impact**	**Mitigating Actions** (what needs to be done to minimise / remove the impact)	**Responsible Officer**

Monitoring of Actions
The monitoring of actions to mitigate any impact will be undertaken at the appropriate level