Family Nursing & Home Care

VACCINE COLD CHAIN POLICY

November 2013

FAMILY NURSING & HOME CARE RATIFICATION FORM

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Policy Amendments

Version No.	Amendments

Copy of this form to be given to Information Governance Officer

1 Foreward

The cold chain refers to the temperature conditions in which a vaccine must be kept from its manufacture to the point at which it is injected into the patient. The correct temperature range for most vaccines is 2-8^{o}C. The cold chain is important as many vaccines are inactivated by freezing, warming may be cumulative and vaccines that are not stored correctly will lose potency.

In November 2006 a cold chain incident led to an Aberdeen surgery becoming the focus of national media coverage. Eight hundred and thirteen patients at the surgery were called for re-vaccination when it emerged that vaccines may have been stored at the wrong temperature for a two year period. As a result of this incident, the Scottish Executive requested three months worth of fridge temperature readings from every GP practice in Scotland.

This cold chain document provides guidance for vaccine storage and handling and includes information, advice and resources that may be helpful. It is important for cold chain procedures to be audited regularly. An audit tool is included as Appendix 1 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.

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2 Cold Chain Management

The cold chain begins when the vaccine is manufactured, moves through to distribution centres and ends with the local immunisation provider at the time of administration. During that period, every effort should be taken to ensure vaccines are transported and stored within the safe temperature range of 2-8^{o}C.

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

- Frozen
- Allowed to get too warm
- Exposed to direct sunlight or fluorescent light

The two essential elements of the cold chain system that ensure vaccine recipients receive potent vaccines are:

- The people managing vaccine storage and distribution
- Use of correct equipment for storing, transporting and monitoring vaccines

Everyone handling vaccines has a responsibility for their potency, irrespective of the stage at which they are involved, be it transport, storage or administration. Training should be given so that individuals understand the importance of complying with the procedures in this document. Wherever vaccines are stored there should be a named designated person (and deputy) who will receive vaccine supplies and monitor their storage.

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®).

3 Vaccine Fridge

It is recommended that vaccines are stored in a purpose-built vaccine fridge (see resources section for details of manufacturers). It is recommended that at least one fridge is dedicated to store vaccines and vaccine emergency drugs.

3.1 Purchasing a Vaccine Fridge

- “Frost free” model refrigerators are recommended for storage of vaccines. Cyclic type domestic fridges are not suitable because they are intended to have wide variations of internal temperature in order to store different food items in different areas and compartments. Domestic fridges also have heating cycles. “Frost free” refrigerators do not have heating cycles but remain “frost free” with low levels of frequent, warming temperatures. Domestic fridges with an integral

ice-box compartment may cause freezing to vaccines that are inadvertently placed near to the ice-box. It should be noted that if a domestic fridge is being used for the storage of vaccines, this is unlikely to be acceptable at a cold chain audit

- Estimate the amount of vaccine required for your clinic's supply period, and choose a fridge that can store this amount in the middle and upper shelves without crowding to allow for adequate circulation of cold air. AT least 50% of the space needs to be filled at all times to stabilise the fridge temperature (containers of cold water can be used to fill space in the fridge if there is not an adequate amount of vaccine)
- Ideally the fridge should be lockable

When a new fridge is delivered, the instruction booklet should be kept safe (and preferably kept with the fridge) as this provides guidance for the read-out of min/max temperatures and information regarding future care and maintenance.

3.2 Location of Vaccine Fridge

- If the fridge is not lockable it should be kept in a safe, restricted access area and in a room that is locked when not in use
- The gap between the rear of the cabinet and the wall should be at least 10cm
- There should be sufficient space for air to circulate around all sides
- The fridge should be placed out of direct sunlight
- The fridge should not be placed near a heat source e.g. radiator, hot pipes, which will adversely affect its working
- Be aware of seasonal changes in the room temperature that may affect the temperature in the fridge

3.3 Maintenance of Vaccine Fridge

- The fridge should be wired directly into the socket, or appropriate steps should be taken to ensure the refrigerator is not accidentally switched off – a label alerting staff should be placed on the plug
- Report any fridge breakdowns immediately so repairs can be made
- Regularly check fridge seals to ensure cold air cannot leak out. If they are brittle or town, arrange for replacement
- If the fridge does require manual defrosting, do this regularly to prevent ice build up which reduces efficiency
- Ensure the area around the fridge (including behind and under) is clean and dust free
- Arrange for regular annual maintenance inspections by the manufacturer or a qualified technician (inspections may need to be more frequent as the refrigerator ages). Records should be kept of any servicing as an auditor is likely to want to see the servicing contract and to ask for evidence of when servicing took place

3.4 Cleaning of Fridge

- If extensive cleaning of the fridge is required, move the vaccines to a second fridge (this temporary storage fridge must also be monitored to ensure the correct 2-8^{o}C temperature is maintained). Alternatively, temporarily store the vaccines in a validated cool-box. If a non-validated pre-cooled insulated container with icepacks is used, the temperature inside the container must be monitored until the normal vaccine refrigerator is ready for use again

4 Temperature Recording

For most medical fridges, the temperature parameters are pre-set prior to it leaving the factory. It is usually advised that a qualified engineer should be contacted if the temperature settings ever need adjusting.

4.1 Minimum/Maximum Temperatures

- 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
- Most modern medical/pharmaceutical fridges have an integral min/max readout mechanism and through a series of steps, the display temperature controls on the outside of the fridge can be used to display the minimum and maximum temperatures reached by the fridge in a set period (that is, in the period since the min/max temperature buttons were previously reset)
- Minimum/maximum temperatures should be read and recorded at least once daily during the working week; preferably at the same time each day (twice daily would be the ideal). A chart should be attached to the front of the fridge so that the min/max temperatures can easily be recorded. Deviations outside of the 2-8°C range should be reported to the designated person responsible for the vaccines (comments, explanations or actions taken should be recorded on the min/max temperature chart). Once the reading of the min/max temperature is complete, the thermometer should be reset to clear the data memory
- If the fridge door is opened for a short time to retrieve vaccines or to place stock into the fridge, warm air will invariably enter the fridge cabinet. The vaccines, however, are unlikely to have changed temperature. It is essential to record the date and time of any door openings on the min/max chart as this will help one to correlate maximum rises in temperature with door opening
- If the vaccine fridge does not have a min/max read-out mechanism, a digital type minimum-maximum thermometer (with probe) must be used
- An alert label should be placed on the fridge door

Points to consider when choosing a thermometer:

- The thermometer needs to be able to measure the current temperature as well as the minimum/maximum temperature over a 24 hour period
- Purchase enough thermometers to allow a separate thermometer for each fridge used for vaccine storage

4.2 Electronic Temperature Data Loggers

- 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

5 Action in 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)

6 Action in Event of Cold Chain Failure

If there is evidence of a suspicion that vaccine has been exposed to temperatures outside the recommended 2-8^{o}C range:

- 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)
- 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
- Contact the hospital pharmacist and/or vaccine manufacturers for advice and guidance
- No vaccines should be used from affected fridge until stability can be guaranteed
- In the unlikely event the pharmacist/vaccine manufacturers deems vaccines affected by the break in the cold chain, the parents of children/young people who have received affected vaccines need to be contacted and rescheduled in consultation with the Immunisation Specialist Nurse or Community Consultant Paediatrician
- Discard sharps bins as directed by Pharmacy
- Incident/near miss policy to be followed

7 Process for Ordering and Receipt of Vaccines

- A childhood vaccine order can be placed weekly
- Complete the order form and fax it to the Pharmacy Department at the General Hospital (Fax 444086)
- The vaccine order form **must** be signed by a designated authorised signatory
- 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 verbally via the Infection Prevention and Control (IPC) Team at Jersey General Hospital. A member of the IPC Team completes an order form on our behalf and arranges its authorisation prior to sending it to the Pharmacy Department.

- Vaccines should be ordered frequently and in small quantities (that is, do not store more stock than is needed)
- Responsibility for this must be designated to a named individual (appoint a named deputy for holidays, sickness etc)
- Delivery of vaccine will be in a Vaccine Porter 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 hospital pharmacist contacted if any products are affected
- Goods received should be checked against the order and any discrepancies reported to Pharmacy 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.

8 Storage

Storing excess vaccine supplies can increase the risk of wastage of the vaccines. This may happen from their being exposed to extremes of temperature which reduces vaccine potency, or wastage due to date expiry of the vaccine. To ensure vaccines are stored safely:

- A designated person should monitor the minimum/maximum temperatures of the vaccine fridge daily (or twice daily) 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

9 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 ???? not sure if this is done when vaccines removed from the fridge or when the surplus is returned or both – please clarify

- 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
- A check and note should be made of the vaccine expiry date prior to use
- Date of administration, brand name of vaccine, batch number of vaccine should be recorded in the medical notes (for vaccines where there is a diluent and powder vial, it is the batch number on the outer vaccine box which should be recorded)
- 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)

10 Spillages

- If spillage of vaccine occurs, gloves should be worn and the spillage soaked up with paper towels. The area should be cleaned according to the local Waste Management Policy
- Gloves, towels etc should be sent for incineration
- Spillages on skin should be washed with soap and water
- Affected eyes should be washed with 0.9% Sodium Chloride Solution Sterile and medical advice sought

11 Disposal of out of Date Vaccines

- Out of date stock should be destroyed by incineration
- Place into a sharps bin (as the Sharps bin will be incinerated)
- If an accountability log is maintained, a record should be made of any vaccine that is disposed of

12 Transporting Vaccines

The Public Health Department, HSS have responsibility and oversee 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.

13 Quality Standards Applicable

(3) – Management of Medicines