NHS
Telford and Wrekin
Clinical Commissioning Group

VACCINE MANAGEMENT AND COLD CHAIN STANDARDS

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1 Introduction

1.1 Rationale for development of this document

Vaccines are biological substances that may lose their effectiveness rapidly if they become too hot or too cold at any time, particularly important during storage and transport of vaccines. All vaccines are sensitive to some extent to light (particularly ultraviolet), heat and cold. Typically vaccines need to be transported and stored in their original packaging at +2^{O}C to +8^{O}C and protected from light.

Maintaining the cold chain (see section 3) ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range until the point of administration.

If the storage recommendations are not followed, vaccine manufacturers can disclaim responsibility for any apparent failure of the product. The standards in this document have been developed to help CCGs and others ensure that manufacturers' recommendations are adhered to, in order to protect individual vaccine recipients.

1.2 Aims

To provide standards for maintaining the cold chain and thereby reducing the risk of compromising the quality and safety of the vaccines administered to patients.

2 Definition – cold chain

The cold chain is standard practice for vaccines throughout the pharmaceutical industry. It can be defined as the storage and transport of pharmaceuticals (including vaccines) requiring controlled low temperature storage between +2^{O}C to +8^{O}C from vaccine manufacturer to the point of administration to a patient.

3 Importance of cold chain maintenance

Maintaining the cold chain during vaccine storage and transport is essential. Poor or inadequate temperature control can reduce the effectiveness of the vaccine leading to lower than expected levels of immune stimulation.

Freezing can cause loss of vaccine potency and increase the risk of local injection site reactions in recipients. Freezing can also produce hairline cracks in the vial, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

Heat also causes loss of potency and reduces the vaccines shelf-life. Vaccine effectiveness cannot be guaranteed unless they have been stored correctly.

4 Standards for vaccine management

4.1 Receipt of vaccines

4.1.1 At least two named, trained people (one from the nursing team and one from management) should be nominated for each clinic as being responsible for the safe storage of vaccines and should work to written procedures developed to meet local needs. These individuals should have a designated deputy to cover in times of absence.

4.1.2 Care should be taken to avoid over-ordering or stockpiling vaccines. Orders should be placed every 2-4 weeks according to need. A stock information system should also be in place to keep track of orders, expiry dates and running total of vaccines. Systems should be developed to ensure stock rotation, and regular checks should be made to remove time expired vaccines.

4.1.3 Using ImmForm will be helpful in making the whole ordering, maintenance and recording process easier and more robust. Registration can be made at: Immform User Registration

4.1.4 If vaccines have been dispatched by post, they should not be accepted by the recipient if more than 48 hours have elapsed since posting. The date and time of dispatch should be clearly marked. If this is not clear the vaccines must not be accepted.

4.1.5 All vaccine orders must be checked as soon as they are received for leakage, damage and discrepancies in the order amounts. In the event of a discrepancy, contact the supplier.

4.1.6 The vaccine brand, quantity, batch numbers and expiry dates should be checked against the delivery sheet and the date and time at which they were received written on the delivery sheet. The delivery must be signed for on receipt.

4.1.7 As soon as they are received, vaccines must be unpacked from the outer cardboard box or paper/plastic delivery bag but must be kept in their original packaging and placed in a suitable designated refrigerator immediately. They must not be left at room temperature.

4.1.8 A record of all vaccines received, their batch numbers and expiry dates should be kept. The delivery sheets can be used as the record and must be retained for 2 years.

4.2 Storage Conditions

4.2.1 The refrigerator must be designed for storage of pharmaceuticals or vaccines and used solely for that purpose. It must be suitable for storage of vaccine between +2 and +8 ^{0}C- a mid-range of +5 ^{0}C is good practice. Ordinary domestic fridges must not be used for vaccine storage.

4.2.2 All vaccines are designated as “Prescription Only” medicines. So fridges must be kept locked or be in a locked room, with restricted public access.

4.2.3 The refrigerator must not be sited near sources of heat e.g. in front of a radiator.

4.2.4 There must be enough space for air to circulate freely around the back of the refrigerator.

4.2.5 The power supply must be secured to avoid disconnection (e.g. wired directly into the socket) or labelled “Do not switch off”.

4.2.6 The refrigerator must be monitored with a digital maximum/ minimum thermometer or a data logging device, which also records the actual temperature.

4.2.7 For refrigerators with external thermometers with a probe, the naked probe should be suitably housed to simulate packaged vaccines and to minimise fluctuations in temperature caused by air movements. This can be achieved by placing the probe in a bottle, according to manufacturer’s instructions. The bottle is then placed inside the refrigerator to mimic storage in vials.

4.2.8 The refrigerator must be regularly cleaned and defrosted according to the manufacturer’s instructions.

4.2.9 Special care should be taken during defrosting to ensure that the temperature of the vaccine does not go outside the specified range. An alternative refrigerator or validated insulated cool box should be used for vaccine storage during defrosting of refrigerators.

4.2.10 Contents should be evenly distributed within the refrigerator to allow air to circulate. Products must not be placed in the door or bottom drawers. The refrigerator must not be overfilled.

4.2.11 Out of date stock must not be stored in the refrigerator.

4.2.12 Storage requirements are described in the manufacturers’ summaries of product characteristics (SPCs). Any use of vaccines that have deviated from recommended storage/transportation conditions is the responsibility of the user.

Vaccines that have gone outside of specified storage requirements should not be used without a risk assessment, based on a thorough understanding of the likely impact of the temperature variation on the effectiveness of the vaccine. These

vaccines should be quarantined, within the cold chain and neither used nor destroyed until advice has been obtained. Quarantined stock must be clearly segregated and made easily identifiable from other stock by labelling “Not to be used”.

Staff should try to determine the length of time the vaccine has been exposed to the adverse temperatures and report to their clinical lead. The manufacturer should be contacted to ascertain the correct course of action to follow.

The incident should be reported to the Medicines Management Team (01952 580438) where further advice can be obtained.

Vaccine not suitable for use must be clearly labelled **‘Do not use – for destruction’** then disposed of as described in section 4.5.

For guidance on reporting vaccine stock incidents see section 4.6

4.2.13 Stock must be rotated according to expiry date and the older stock positioned at the front of the refrigerator. Due to the risk of fridge failures and as vaccines have an expiry date Public Health England recommend that organisations only order enough vaccines to maintain a two to four week stock level.

4.2.14 Unused vaccines from a clinic session which have been stored between 2 - 8ºC may be returned to the refrigerator for future use (vaccines should not be taken out for a session more than twice). They must be marked and dated so that they will be the first stock used at the next session. If a marked vaccine is still unused at the next immunisation session, it should be discarded. If the storage criteria have not been met during a session, stock must not be returned for reuse. To reduce waste, a minimum amount of stock should be removed from the refrigerator or cold box at a time.

4.2.15 Refrigerators should be assessed quarterly and any issues documented, this is a routine check to monitor fridge temperature, storage procedures and handling procedures.

4.2.16 Systems should be in place to include risk assessment of refrigerators and a schedule of inspection, calibration and maintenance. The interval between inspections should comply with the manufacturer’s instructions. Inspection, calibration and maintenance should be recorded. GP Practices are responsible for arranging their own risk assessment of equipment and a schedule of inspection, calibration and maintenance.

4.2.17 Expiry dates can be affected by poor vaccine handling and may mean that the administered vaccine is ineffective.

4.3 Monitoring the refrigerator

4.3.1 A named individual and named deputy must be responsible for monitoring the refrigerator. It is important that the person making the recording does it at the same time every day during the working week and signs the Refrigerator Monitoring Sheet (Appendix 1) and acts promptly if the temperature falls outside +2 to +8 ^{0}C.

4.3.2 The temperature within the refrigerator must be monitored continually with a maximum-minimum thermometer. All fridges should ideally have two max/min thermometers, with one independent of mains power.

4.3.3 The following must be monitored and recorded each working day on the Refrigerator Monitoring Sheet (Appendix 1):

- The maximum temperature
- The minimum temperature
- The actual temperature

4.3.4 The calibration of thermometers should be checked annually to ensure that they are working correctly. However if only one max/min thermometer is used, then a monthly check should be carried out to confirm that the calibration is accurate.

4.3.5 The thermometer must be reset after each reading is made. 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.

4.3.6 For practices/clinics using data logging devices: The data logging device must be checked on a daily basis to ensure the alarm has not been triggered, a record of this check should be kept for audit purposes. If an alarm has been triggered, data should be downloaded to confirm the max/min temperatures and the length of time the fridge remained outside the required range. If the alarm has not been triggered the data logger can remain in the fridge and the data downloaded on a weekly basis. All users must be aware of how to download and use the data logging device. Calibration and maintenance will need to be performed as outlined by the manufacturers, at a minimum an annual calibration check must be carried out.

4.3.7 Arrangements must be in place for back-up facilities to be available in the event that the refrigerator fails or breaks down**.**

4.3.8 Routine maintenance should include the following:

- Maintaining the fridge in a clean condition
- Ensure that there is a maintenance contract that allows for at least yearly servicing and calibration of temperature gauge.
- The temperature is calibrated at least every month against an independently powered external thermometer.
- A routine vaccine management review is performed quarterly.
- Maintenance of the cold chain forms part of all immunisation training updates.

4.3.9 In the event of the refrigerator temperature falling outside the limits of +2 to +8 ºC advice should be sought from the manufacturer regarding the viability of any vaccines stored. If further advice is required the Medicines Management Team may be contacted (01952 580438).

4.4 Transporting vaccines for an immunisation session

4.4.1 An approved cool pack/box must be used for transporting vaccines requiring cold storage, packed in accordance with the manufacturer's instructions. Domestic cool boxes are not suitable. Details of suitable vaccine porters can be found at:

Helapet Cold Chain Solutions

Other manufacturers produce similar products.

4.4.2 Vaccines must be kept in the original packaging, wrapped in bubble wrap and placed into a cool box with cool packs as recommended by the manufacturer's instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from damage, such as being frozen.

4.4.3 The time between removing vaccines from cool storage and use must be kept to a minimum.

4.4.4 The vaccine re-packaging protocol must be followed when re-packing vaccines for transportation.

4.4.5 A max/min thermometer should be used to monitor the temperature while the box is in use

4.5 Vaccine disposal

4.5.1 Careful consideration should be given to minimising levels of stock held, as unwanted vaccines cannot be returned to stock.

4.5.2 For vaccines that have been reconstituted for immunisation, at the end of an immunisation session any remaining reconstituted vaccine must be placed in a sharps bin for incineration.

4.5.3 Vaccines that are time expired, no longer suitable for use, used or partially used vaccine ampoules or vials should be disposed of by incineration at a suitably authorised facility.

4.5.4 Used or partially used vaccine ampoules or vials may be safely disposed of by sealing in a puncture resistant 'sharps' container. If 'live' vaccines are to be disposed of the 'sharps' container should be marked "contains live vaccine'

4.6 Reporting Vaccine Wastages

4.6.1 All vaccine wastage must be recorded using the 'Stock Incident Capture' form available on ImmForm.

4.6.2 To access the 'Stock Incident' report you will need to login on to the 'Vaccine Supply System' on ImmForm. When on the site, click the 'Stock Incident' tab, and select 'Stock Incident Capture'

4.6.3 Record the date of the incident and then the reason for the vaccine wastage. Include any further description of the stock incident where necessary.

4.6.4 Record the number of vaccines doses lost / destroyed

4.6.5 Order replacement vaccines as you normally would via ImmForm BUT only if you have suitable replacement/repaired cold chain storage capacity.

For further guidance click on the link below
ImmForm Fridge failures and stock incidents

4.7 Spillage

4.7.1 Every location where vaccines are to be administered should have copies of the Control of Substances Hazardous to Health (COSHH) safety data sheets for the vaccines used, and a spillage kit.

4.7.2 If spillage of vaccine occurs, gloves should be worn and the spillage soaked up with paper towels immediately.

4.7.3 Any broken glass (sharp) waste should be disposed of using a 'sharps box' and the protective clothing or mopping up materials used may be disposed of in yellow clinical waste bags.

4.7.4 Spillage on skin should be washed with large amounts of water. Report to Occupational Health for further medical advice, and complete an incident form.

4.7.5 Affected eyes should be irrigated well, preferably with sterile 0.9% normal saline.

4.7.6 If the spillage was of a 'live' vaccine, disposal should be in accordance with the procedure for disposal of 'live' vaccine as advised in the disposal section above.

4.8 Information Sources

- Immunisation against Infectious Disease. DH, London, chapter 3: Storage, distribution and disposal of vaccines. Available at http://www.dh.gov.uk/greenbook/

- Individual PGDs for vaccines

- Individual Summary of Product Characteristics (SPCs) supplied by the manufacturer of the pharmaceutical. Available at www.emc.medicines.org.uk

- DH Immunisation website Immunisation - Public Health England - GOV.UK

5 Audit

5.1 GP practices, clinics and health centres will undertake the following self-audit:

- Temperature monitoring and recording of the actual, the maximum and the minimum temperatures on each working day

- Each week check the contents of the fridge at least once.

- Each month vaccine stock should be audited and recorded.

- Every three months, audit records of stock and temperature management

6 Reference sources used to produce this document:

1. DH, *Immunisation against Infectious Disease. A*vailable at http://www.dh.gov.uk/greenbook/

2. John Taylor, MCA, *Recommendations on the Control and Monitoring of Storage and Transportation Temperatures of Medicinal Products*. The Pharmaceutical Journal 2001; 267; 128-131

3. DH Protocol for ordering, storing and handling vaccines Gateway number 14721 Nov 2010

4. Public Health England July 2014: ImmForm Fridge failures and stock incidents

APPENDIX 1 REFRIGERATOR MONITORING SHEET

MONTH ………..
CLINIC……DEPARTMENT/SPECIALITY……
DESIGNATED STAFF……RESERVE STAFF……..

DATE	ACTUAL	MAXIMUM	MINIMUM	RESET THERMOMETER	TIME READING TAKEN	INITIALS	GUIDELINES
	BETWEEN 2° - 8°C	**NOT ABOVE 8°C**	**NOT BELOW 2°**	**Yes/No**			Has the refrigerator been disconnected / turned off / or has there been a power cut? Has the refrigerator door been left open? Has the refrigerator been opened frequently in the last few hours or was there a session the previous day? Is the thermostat set too high or too low? (If applicable). Was the thermometer reset correctly after the last reading? If used, is the temperature probe correctly placed in a bottle of water inside the refrigerator? (if applicable). Is the refrigerator more than half full? Does the refrigerator need defrosting? (if applicable) Has the thermometer been accidentally damaged e.g. fallen off the refrigerator? Does the refrigerator need servicing?
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Important Notice

If the refrigerator temperature readings are outside the required range (+2° to +8°C), seek advice from the manufacturer as soon as noticed regarding the viability of any vaccines stored. For further advice please contact the Medicines Management Team (01952 580438).

Also check the points in the guideline section.

Please NOTE Original Refrigerator Monitoring Sheets should be kept for TWO YEARS.

APPENDIX 2

Cold Chain Audit Tool

GP Practice:	Audit completed by (Print Name, Position & Sign)
Date of Completion:	

- Work through each of the questions below and tick box, yes or no as appropriate.
- If you have ticked all white boxes then the audit is complete and no further action is needed.
- If you have ticked any boxes that are shaded grey it means that you are not following cold chain guidance and action must be taken in order to demonstrate compliance
- Set a time scale to address any action(s) and repeat the audit.

Policies and Procedures	Yes	No
1. Does the practice have an up to date cold chain policy (reviewed within the last two years) that is visible and accessible to all staff?		
2. Have all staff handling vaccines, from receipt to administration, been trained to follow policies to ensure cold chain compliance?		
3. Are there at least two named, trained people (one from the nursing team and one from management) that have overall responsibility for correct storage and transport of vaccines?		
4. Is there a quarterly review of cold chain practice?		
Ordering and Monitoring of stock	Yes	No
5. Are vaccine stocks monitored prior to ordering?		
6. Are vaccine stock levels appropriate to practice requirements?		
7. Is there a stock information system in place to keep track of orders, expiry dates and running total of vaccines?		
8. Are the expiry dates of vaccines monitored and close to expiry stock clearly labelled?		
9. Is out-of-date stock clearly labelled, removed from the refrigerator and destroyed promptly?		
Receipt of Vaccines	Yes	No
10. Are vaccines checked against the order for discrepancies and leakage or damage before signing for them?		
11. Is there a procedure for recording the date and time at which vaccine types, brands, quantities, batch numbers and expiry dates were received?		
12. Are vaccines refrigerated immediately on receipt?		
13. Are the completed, signed delivery sheets retained for two years?		
Vaccine refrigerator(s) (if several fridges are used only tick white box if it applies to all)	Yes	No
14. Is the refrigerator specialised for the storage of pharmaceutical products?		
15. Is the refrigerator of adequate size to store correctly the volume of vaccines required (Should be sufficient space to allow air to circulate around the vaccine packages), including during times of increased demand, e.g. annual influenza programme?		
16. Is anything other than vaccines/medicines stored in the refrigerator (including specimens, food & drink)?		

17. Is the refrigerator either both lockable and also locked or in a locked room?		
18. The vaccine refrigerator/ the room where the refrigerator is kept locked at all times with access to authorised staff only (COSHH 2002)		
19. Is the refrigerator properly ventilated and not located near any heat source, e.g. radiator, window?		
20. Is the electricity supply safe, e.g. switchless plugs or cautionary notices in place?		
21. Are there arrangements in place in the event of a refrigerator failure or power cut including backup facilities?		
22. Are there records of regular servicing, calibration and defrosting within the last 12 months or as per manufacturer's instruction?		
23. Is the refrigerator kept clean (no evidence of any spills)?		
24. Is there an approved cool box with appropriate temperature monitoring or alternative refrigerator available to store vaccines during servicing, defrosting and cleaning?		
25. Are vaccines stored in the door, bottom drawers or adjacent to the freezer plate?		
Refrigerator thermometers	Yes	No
26. Is the temperature continually monitored with a maximum– minimum thermometer?		
27. Is there a second min/max thermometer independent of mains electricity supply in the fridge?		
28. Are the minimum, maximum and actual temperatures in the refrigerator monitored and recorded at least once each working day (Ideally the same time each day)? Acceptable temperature range of **+2 and +8°C. A mid-range of 5°C is good practice.**		
29. Are thermometers reset after being read, according to the manufacturer's guidance?		
30. Are temperature records readily accessible and retained for audit purposes?		
31. Are thermometers calibrated at least every month against an independently powered external thermometer and serviced annually?		
32. Is the temperature check log kept by the refrigerator?		
Storage of Vaccines	Yes	No
33. Are there systems to minimise refrigerator door opening during immunisation clinics?		
34. Are vaccines stored in the manufactures original packaging?		
35. Is there evidence of stock rotation (check weekly)?		
36. If you need to transport vaccines to outlying clinics, schools etc. do you use validated cool boxes with maximum-minimum thermometers and cool packs? (only complete if applicable)		

This tool should be used in conjunction with Immunisation against Infectious Diseases, (The Green Book 2006), chapter 3, Storage, distribution and disposal of vaccines and the DH Protocol for ordering, storing and handling vaccines (https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3)