



Vaccination Transport and Storage Policy

Document Status	Final
Version:	V3.0

Document Change History		
Initiated by	Date	Author (s)
Occupational Health and Wellbeing Manager		Sarah Greatorex
Version	Date	Comments (i.e. viewed, or reviewed, amended approved by person or committee)
V1.1	12 March 2012	Review by HR Policy Group
V1.2	1 June 2012	Sent to SPF for approval
V1.3	August 2012	Sent to EMT for approval
V2.0	30 October 2012	Approved
V3.0	10 December 2015	Approved extension to review date by SPF to June 2016

The Trust will not tolerate unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups.

Document Reference	HR Directorate
Recommended at Date	Staff Partnership Forum 1 June 2012
Approved at Date	Executive Management Team
Review date of approved document	June 2016
Equality Impact Assessment	Completed
Linked procedural documents	Disciplinary Policy (Managing Conduct and Performance) Health and Safety Policy Infection Control Policy
Dissemination requirements	All managers and staff, via staff bulletins and the intranet

Checklist completed	Yes / No? YES
Part of Trust's publication scheme	Yes / No? YES

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1. Policy Statement

1.1 This document outlines the Vaccination Transport and Storage Policy for The East of England Ambulance Service NHS Trust (the Trust). The Trust wishes to ensure that, so far as is reasonably practicable and in conjunction with Department of Health (DoH), National Patient Safety Agency (NPSA) and Health Protection Agency (HPA) policies that:

- Health care workers are protected by immunisation from acquiring disease from patients/clients;
- Patients/clients are protected from the risk of acquiring disease from healthcare workers (NB if this can be prevented by immunisation of employees).

Details of the immunisation requirements for employees are contained in the Trust's Infection Prevention and Control Management Policy.

1.2 This policy states how vaccines used by Occupational Health are safely stored and handled within the Trust, and describes how the cold chain is maintained within the Trust and to clearly specify responsibilities within the cold chain. Vaccine efficacy depends on maintaining the vaccine 'cold chain' at every stage from the manufacturer to the recipient.

1.3 This policy has been written in partnership by management and staff side.

2. Scope

2.1 This policy applies to all employees responsible for the vaccination of other Trust employees or Trust volunteers. This policy will largely apply to

Occupational Health employees but may also include other clinicians within the Trust if they are running vaccination clinics on Occupational Health's behalf.

- 2.2 Under the Health and Safety at Work Act, individual employees are responsible for ensuring that they undertake their duties in a safe manner without endangering themselves, other employees or patients.
- 2.3 Non-compliance with this policy may lead to further action, which for employees may include formal disciplinary action.

3. Access to the Procedure

- 3.1 All employees are entitled to access to this policy which is located in the HR Policies and Procedures Folders and/or on the Trust's Intranet. However, if you require this policy in any other format please seek guidance from the Human Resources Department, your line management or trade union representative.
- 3.2 Employees and Managers may also wish to consult related Trust policies or associated documents such as Disciplinary Policy (Managing Conduct and Performance), the Department of Health's "Green book" Immunisation Against Infectious Diseases, the Health and Safety at Work Act 1974, Health and Safety Policy, Infection Control Policy, National Patient Safety Agency Rapid Response Report January 2010, National Patient Safety Agency Vaccination Cold Storage January 2010, Association of National Health Occupational Physicians (ANHOPS) Guidance on Immunisation of Health Care Workers.

4. Roles and Responsibilities

- 4.1 The Board is responsible for ensuring that there is a Vaccination Storage Policy in place and that it is implemented.
- 4.2 The Medical Director is responsible for advising the Trust on matters related to vaccination storage.
- 4.3 The Pharmacist Lead is responsible for ensuring that Patient Group Directives (PGDs) for vaccines clearly specify how the vaccine should be stored, in accordance with manufactures' guidance and for advising the Trust on matters related to vaccination storage.
- 4.4 The Health and Wellbeing Manager is responsible for:
 - ensuring that the Occupational Health employees involved in the storage and handling of vaccines understand their responsibilities under this policy and adhere to the policy;
 - the purchase of appropriate equipment required for the Trust to maintain the vaccine cold chain;
 - the review of this policy in light of new DoH or other relevant guidance;

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- the completion of any incident forms should a problem occur regarding vaccination cold chain storage;
 - ensuring that any other clinical employees who may be involved in administration of vaccines on behalf of Occupational Health, are aware of their responsibilities to adhere to this policy;
 - completion of yearly audits of vaccination storage procedures and reviewing practice as required (Appendix A).

4.5 Occupational Health will provide immunisations for health care workers as specified in the Department of Health's "Green book" Immunisation Against Infectious Diseases.

4.6 It is Occupational Health nurse advisor's role to:

- follow the storage instructions on the vaccine PGDs, in this policy and in conjunction with the manufacturers' Summaries of Product Characteristics (SPCs);
- order the relevant vaccinations in sufficient quantities;
- monitor the temperature daily of the drugs fridge;
- maintain a log of vaccines (see Appendix B);
- if transporting vaccinations, to use the cool boxes provided and monitor temperature of cool box on an hourly basis;
- know what action to take should a problem occur with vaccine cold chain storage and how to report the incident;
- attend any relevant training as required by the Trust which would aid their understanding of this policy;
- act in accordance with Royal College of Nursing guidance;
raise any concerns regarding this policy or issues with faulty equipment with the Health and Wellbeing Manager

Each nurse is known as the "designated person" as is responsible for the ordering, receipt and storage of vaccines. It is acceptable to the Trust that the nurse can nominate a "deputy", i.e. another nurse to receive and store the vaccines in their absence (and has suitable access);

4.7 It is the Occupational Health Administration team's role to:

- know what action to take should a problem occur with vaccine cold chain storage and how to report the incident;
- raise any concerns regarding this policy with the Health & Wellbeing Manager.

4.8 The Human Resources Department is responsible for keeping the provisions within this policy in line with employment legislation, best practice people management principles and NHS guidelines.

4.9 Managers, HR staff and trade union representatives are responsible for providing advice and guidance to employees on the application of this policy and procedure.

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- 4.10 Management and trade union representatives are responsible for bringing any mutually beneficial improvements to this policy to the attention of the Trust.

5. Definitions

- 5.1 Cold chain – is the name given to the system of transporting and storing vaccines within the safe temperature of 2-8 degrees centigrade. The cold chain involves all people, equipment and procedures which ensure an effective vaccine is administered to those who need it.
- 5.2 Vaccinator – the clinician who will administer the vaccine to the member of employees/Trust volunteer.

6. The Procedure for Safe Storage of Vaccines

- 6.1 At all times Trust policy will follow national DoH policy for the ordering, storage, stock control, distribution, transport and disposal of vaccines, as set out below.
- 6.2 Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transportation and storage. Vaccines naturally biodegrade over time and storage outside of the recommended temperature range –(including during transport and storage) may speed up loss of potency, which cannot be reversed. This may result in the failure of the vaccine to protect, as well as resulting in vaccine wastage.
- 6.3 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.

Storage

- 6.4 Vaccines should be stored in the original packaging between +2°C to +8°C and protected from light, as exposure to ultraviolet light will cause loss of potency. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Ordering and Monitoring of Stock

- 6.5 Care must be taken in ordering vaccines, especially as certain vaccines are packaged in multiple quantities. Occupational Health must only order what is required. Best practice is to order small quantities on a regular, scheduled basis, the exception to this would be yearly seasonal flu vaccine. The OH nurse placing the order must ensure they know when the vaccines will be delivered and be available to receive the vaccines or have nominated a deputy (another clinician) to receive vaccines on their behalf.

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- 6.6 Vaccine stocks should be reviewed monthly by the Occupational Health Nurses to avoid over-ordering or stockpiling.
 - 6.7 Any out-of-date stock should be labeled clearly, removed from the refrigerator and destroyed as soon as possible in accordance with this policy.
 - 6.8 It is the responsibility of the individual vaccinator to ensure that vaccines are never used when past their expiry date.

Receipt of Vaccines

- 6.9 On receipt of vaccines, the Occupational Health Nurse Advisor must check them against the order for discrepancies and leakage or damage before signing for them.
- 6.10 Vaccines must be refrigerated immediately after checking (see 6.4 above) and must not be left at room temperature.
- 6.11 Vaccine types, brands, quantities, batch numbers and expiry dates should be recorded with the date and time at which the vaccines were received (see Appendix B).
- 6.12 Vaccine stocks should be placed in the refrigerator in order so that those with shorter expiry dates are used first, using best stock rotation principles.

The Vaccine Refrigerator

- 6.13 The Trust has provided specialised refrigerators for the storage of pharmaceutical products which must be used for vaccines and diluents. Vaccines must never be kept in an ordinary domestic refrigerator. 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.
- 6.14 Vaccines must never be stored in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator. Sufficient space should be allowed in the refrigerator so that air can circulate freely.
- 6.15 All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Refrigerators must either be lockable or within a room that is locked when not occupied by an employee. Vaccines should never be left unattended at outlying clinics. Individual vaccinators are responsible for ensuring that if working off-site that the cool box cannot be tampered with.
- 6.16 The accidental interruption of the electricity supply should be prevented by placing cautionary notices on plugs and sockets.
- 6.17 Refrigerators should not be situated near a radiator or any other heat source that could affect their working, and should be appropriately ventilated. The top surface of the refrigerator is not to be used for storage.

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- 6.18 Ice should not be allowed to build up within the refrigerator, as this reduces effectiveness. The responsibility for defrosting and cleaning the vaccine refrigerator lies with the Occupational Health Nurse Advisor, minimally on an annual basis. It is their responsibility to maintain records of the cleaning and defrosting for audit.
- 6.19 An approved cool box (with appropriate temperature monitoring) or an alternative refrigerator should be used to store vaccines during defrosting of the main refrigerator. Vaccines should only be replaced once the refrigerator has returned to the correct temperature after defrosting.

Refrigerator Thermometers

- 6.20 The temperature within the vaccine refrigerator must be continually monitored with a digital maximum–minimum thermometer. This will identify when the temperature may have been outside of the recommended range.
- 6.21 Temperatures in the refrigerator must be monitored and recorded by the Occupational Health Nurse Advisor (or their nominated deputy) at least once each working day, and documented on a chart for recording temperatures. An example can be found in Appendix B.
- 6.22 The Health and Wellbeing manager is responsible for arranging for the calibration of thermometers and they must be checked annually to ensure that they are working correctly. The records should be readily accessible for easy reference and retained until the next audit.
- 6.23 If the vaccine refrigerator thermometer shows that the vaccines have been stored outside of 2-8 degrees, the Occupational Health Nurse Advisor must:
- record on the log any known reasons for fluctuations in temperature;
 - quarantine any exposed stock until assurance received from manufacturer;
 - contact the manufacturer for advice giving details of temperatures and time exposure;
 - ensure manufacturer's responses are documented;
 - if issue with temperature control cannot be resolved promptly, then vaccines must be moved to another suitable location;
 - if this is not possible, they must be disposed of in accordance with this policy.

The Use of Cool Boxes

- 6.24 Due to the large geographical area of the Trust, vaccines will be administered by Occupational Health (or other clinicians working as vaccinators) at Trust premises which do not have a vaccine fridge. Therefore vaccines need to be transported to and from Trust sites safely, as well as stored correctly at the vaccination clinic to maintain the cold chain. The Trust will provide each vaccinator with a suitable validated cool box that has a digital thermometer and that will alarm if temperature moves out of the permitted range. The cool box can be powered by mains electricity or via a vehicle power outlet, with cool packs as back up.

6.25 It is the responsibility of the vaccinator to ensure that:

- the cool box should be within the correct temperature range before the vaccines are placed inside;
- the temperature is maintained by the swift transfer from site to car, car to clinic etc;
- the temperature is monitored hourly by the vaccinator;
- bubble wrap is placed between the cool packs and the vaccines;
- an appropriate number of vaccines are taken to avoid unnecessary wastage;
- at the end of the vaccination clinic, unused vaccines which have NOT been removed from the cool box should be returned to a vaccination refrigerator on the same day and marked “use first”. Such vaccines should not be re-stored in this way a second time;
- as cool boxes can be heavy to carry a trolley should be used where possible to minimise the risk of back strain/injury.

The Use of Other Clinicians to Administer Vaccination Clinics

6.26 To support mass vaccination programmes such as seasonal flu, Occupational Health may request that other clinicians (either nurses, paramedics or ECPs) administer vaccines on OH’s behalf.

6.27 These vaccinators must:

- have signed any relevant Trust PGD;
- attended any relevant training;
- act at all times in accordance with this policy;
- have access to the necessary equipment to maintain the cold chain;
- raise any concerns they may have about the vaccination programme or the cold chain with the Health and Wellbeing manager.

Vaccine Spillages

6.28 Spillages must be cleared up as soon as possible by the vaccinator. Gloves should be worn and the spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles. The area should be cleaned in accordance with the Trust Infection Prevention and Control Management Policy. Gloves, paper towels etc should be sent for incineration. Any spillages should be reported to the Health and Wellbeing Manager and an incident report form completed.

Disposal of Vaccines

6.29 All reconstituted vaccines and opened single and multi-dose vials must be used with the recommended period by the manufacturers or should be disposed of at the end of an immunisation session by sealing them in a proper, puncture resistant sharps box (UN approved BS7320). The sharps container should be replaced once it is two-thirds full and should not be accessible to any unauthorised individual.

Procedure for Dealing with an Accidental and Temporary Disconnection of the Electric Supply

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- 6.30 The person identifying the problem is to record the current refrigerator temperature.
 - 6.31 If it is inside the range of 2 – 8 degree centigrade, reconnect the power supply and no further action is required, other than to log incident happened.
 - 6.32 If outside the range 2-8 degree centigrade, reconnect the power supply, taking note of the time that you do this. Try to establish how long the vaccines may have been outside the range and check for any previous breaks in the cold chain. Establish the number and types of vaccines in stock in the fridge and contact their manufacturer.
 - 6.33 In the event of a prolonged power failure the provided cool boxes should be used as a temporary measure whilst a suitable alternative refrigerator can be located

Audit

- 6.34 At any time, the vaccine logs will be made available to the Trust upon request.
- 6.35 The Health and Wellbeing Manager is responsible for completing an annual audit, using the Audit tool in Appendix A.

7. Policy Review

- 7.1 This policy will be reviewed every three years or amended in the light of new employment legislation and/or relevant case law.

Annual Audit of Vaccination Policy, to be completed by the Health and Wellbeing Manager, one per vaccination fridge.

Date of Audit:

Manufacturer and location of Vaccine fridge:

		Yes	No	N/A	Comments
1.	Vaccines are stored immediately upon delivery to fridge?				
2.	Fridge is fit for purpose and is not a domestic fridge?				
3.	The fridge has clear label on power socket to avoid fridge being accidentally turned off?				
4.	The fridge has a digital thermometer that shows external and internal temperatures?				
5.	Temperature checks are performed and recorded daily				
6.	Recorded temperatures are within the acceptable range of between 2 and 8 degrees centigrade				
7.	The vaccine log has been fully completed and available for audit?				
8.	The fridge only contains vaccines and diluents (COSHH)?				
9.	The vaccines are not stored in the door of fridge or in a separate drawer at the bottom of the fridge?				
10.	Storage of vaccines in fridge is adequate i.e. up to 50% full				
11.	Alternative and appropriate storage is available in the event of a breakdown of fridge?				
12.	A safe system is in place for the disposal of expired/surplus/damaged vaccines?				
13.	All vaccines are in date?				

14	Vaccine stocks are rotated and used according to date?				
15	The top surface of the fridge is not used for storage?				
16	There is a named responsible person for the overall safe use, storage and transport of vaccines from this fridge?				
17	The OH nurse has attended training on the guidance for vaccine use, storage and maintenance of the cold chain				
18	The fridge's thermometer has been calibrated/PAT tested within past year?				
19	Has the fridge had its annual defrosting and/or cleaning?				

Appendix B

Vaccination Refrigerator Log – one to be completed for each Vaccination Refrigerator

Vaccine Name	Vaccine Concentration	Batch number	No. Of Doses per vial	Number of vials	Date received	Time received	Signature of recipient	Date removed from fridge	Time removed from fridge	Signature	Purpose e.g. clinic, transfer to another fridge	Time spent out of fridge	Signed back in by

Step 1:	Identify main aims of policy
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Describe the main aim, objectives and intended outcomes of the proposed project/policy

<p>Aim:</p> <p>To outline the process for the safe storage and transportation of vaccinations</p>
<p>Objectives:</p> <ul style="list-style-type: none"> - To ensure the cold chain is maintained - Responsibilities for those handling vaccinations is clear
<p>Intended Outcomes:</p> <p>To ensure that vaccinations are safely stored and transported to ensure they are effective and wastage is limited</p>

Step 2:	Collect and Analyse Information
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Has any previous work or research been done on equality issues in the area of the proposed project/policy? If so, what were they?

No			
You should ask relevant questions in relation to all the strands equality & diversity, but information gathered should be relevant to your needs that will inform your decisions around the topic you are reviewing. If you identify a need for information that is not available you should consider and plan with the relevant others how this information could be obtained ¹			
Gender including transgender	Do you have enough information?	Yes	No
	What else do you need to know?		
Race	Do you have enough information?	Yes	No
	What else do you need to know?		
Disability	Do you have enough information?	Yes	No
	What else do you need to know?		
Sexual Orientation	Do you have enough information?	Yes	No
	What else do you need to know?		
Age	Do you have enough information?	Yes	No

¹ Refer your need for information and proposal to the Equality & Diversity Steering Group using a copy of this page with your information before proceeding to ensure all similar requests can be coordinated
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	What else do you need to know?		
Religion & Belief	Do you have enough information?	Yes	No
	What else do you need to know?		

Step 3: Identify the level of impact

To help you think about this, you should complete the High, Medium, Low table and give reasons/comments for where:

- (a) The policy/strategy/project could have a positive impact on any of the equality target groups or contributes to promoting equality, equal opportunities and improving relations within equality target groups.
- (b) The policy/project/procedure could have a negative impact on any of the equality target groups, i.e. disadvantage them in any way. **If the impact is high, a full Equality Impact Assessment should be completed.**

Equality	a. Positive impact			b. Negative impact			c. If NONE how did you evidence this?
	Low	None	High	Low	None	High	
Gender (including transgender)		None		Yes			Applicable to all
Race		None		Yes			Applicable to all
Disability		None		Yes			Applicable to all
Sexual orientation		None		Yes			Applicable to all
Age		None		Yes			Applicable to all
Belief and Religion	Yes			Yes			

Step 3^a: Decide if policy is equality relevant

Does the proposed project/policy have an explicit focus on inequalities, human rights and diversity? If so, how?

No

Is there a risk that the proposed project/policy may unintentionally mask or cause a negative impact on equality and diversity?

Yes

Is there a risk of adverse impact? If yes, please list the specific risks. If no, please explain the basis of your judgement.

Risk of detrimental treatment in managing people with different beliefs,

Step 3^b: Record findings and produce action plan

If there are any potential or actual risks, what action will be undertaken to mitigate the specified risks, or to minimise the adverse impact. Within what timescales will this be done, what are the implications on resources and who will be responsible?

Findings	Proposed action	Timescale	Implications on resources	Responsible lead

Please state how the policy, procedure or process will be monitored for inequalities that may arise after the implementation:

This policy will be reviewed after three years

Summary:

On the basis of the information/evidence/consideration so far, do you believe that the proposed project/policy will have a positive or adverse impact on equality or diversity? (please circle one)

Positive Impact	Adverse Impact
Yes	

Basis for your judgement:

There is a clear process for applying for an employment break. Decisions can be appealed against allowing opportunity for the information to be reviewed again.

Has a significant adverse impact been identified that requires a Full Equality Impact Assessment?

YES	Some Impact Identified	NO
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Name of the project/policy lead completing this assessment:

Name: :Laura Norton

Job Title: Human Resources Business Partner

Signature:	Date: 13 th September 2011
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**Please email this completed draft document to the Equality & Diversity Lead for quality assurance purposes and record monitoring.
*This form must accompany all policies and procedures when sent to Trust Board Committee or Group for approval***

Executive Summary Page for Equality Impact Assessment:

Document Reference:	Document Title: Vaccination Transport and Storage Policy
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Assessment Date:	Document Type: HR Agreement
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Responsible Director: Lesley Bradley	Lead Manager: Tracey Leghorn
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Conclusion of Equality Impact Assessment:

Recommendations for Action Plan:

Risks Identified:

Approved by a member of the executive team:

YES	NO
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Name: Lesley Bradley	Position: Director of Business Transformation
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Signature:	Date:
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This whole document should be stored with the master document and a final approved copy must be sent to the Equality & Diversity Lead at Bedford Office