Policy for Vaccine Storage and Handling

Issue Date: November 2007

Reviewed: November 2008 December 2009 January 2012
Next review date: January 2014

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Document Control Sheet

Name of Document:	Policy for Vaccine Storage and Handling
Version:	4
File location\Document name:	
Date of this version:	January 2012
Produced by:	Infection Prevention and Control Team
Reviewed by:	IPACC Prescribing team
Synopsis and Outcomes of Consultation Undertaken:	Reference to key guidance documents
Synopsis and Outcomes of Equality & Diversity Impact Assessment	No specific issues. National EIA gives more details on measures to reduce HCAIs.
Board/committee approval at meeting on:	JICC February 2009 PEC March 2009 Community Services IGC 28/3/2009 JICC 12/1/2010 IPACC 22/2/12
Publication date:	
Distribute to:	Clinical staff
Date distribution completed:	
Due for review by Board/committee no later than:	January 2014
Enquiries to:	gyw-pct.infectionprevention@nhs.net

Revision History

Date	Summary of changes	Author(s)	Number
Jan 2012	Logo changed	IPCS	4

Approvals

Committee	Date	Number

1. Introduction

Vaccine efficacy depends on maintaining the vaccine 'cold chain' at every stage from the manufacturer to the recipient.

Vaccines are biological substances, that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage. Vaccines naturally biodegrade over time, and storage outside of the recommended temperature range – including during transport and storage – may speed up this loss of potency, which cannot be reversed. This may result in the vaccine failing to protect, as well as resulting in vaccine wastage.

Inactivation of vaccines may only come to light when immunised individuals acquire the disease in question. It may then be difficult to demonstrate a clear link between this and previous inadequate storage, distribution and handling practices

Each stage in the cold chain should be the subject of careful quality control, not least in the general practice setting.

High standards are necessary and are encouraged in primary care by appropriate training of staff involved with immunisation, clear designation of responsibilities to named individuals, the development and implementation of written protocols, and continuing regular audit.

2. Purpose and scope

This document applies to all staff employed by East Coast Community Healthcare CIC (ECCH). These staff may work within ECCH premises, patients own homes, or care settings owned by other agencies. Others (GP Practices) may choose to adopt this policy as their own this should be documented at a suitable meeting as the agreed policy.

3. Policy Statement

This policy will be implemented by all Staff to ensure adherence to best practice.

4. Responsibilities

It is the responsibility of all staff to ensure that they adhere to best practice

5. Policy monitoring

It is the responsibility of all department heads/professional leads to ensure that the staff they manage adhere to this policy.

6. Review

This policy will be reviewed by the Infection Prevention and Control Team in conjunction with the prescribing team.

7. Safe vaccine storage

- A storage refrigerator must be dedicated to vaccines and medicines only. It is recommended that an additional vaccine storage refrigerator is available to cover periods of particularly high usage, (e.g. the influenza immunisation period).

- Vaccine storage, and the associated record keeping, should be delegated to a named individual (and alternate{s}).

- Vaccines should be placed, as appropriate, in their original packaging, in the storage refrigerator **immediately** on receipt. Vaccine stocks should be placed within the refrigerator so that those with shorter expiry dates are used first. **Vaccines must never be used when past their expiry date.**

- Sufficient space should be allowed in the refrigerator to allow circulation of cool air.

- A log book of all vaccine batch numbers and expiry dates should be kept

- Vaccines must be kept within the temperature range recommended by the manufacturer (usually 2-8 degrees Centigrade for injectable vaccines. Vaccines must **never** be frozen.

- Refrigerator temperatures should be monitored/recorded daily using a maximum/minimum thermometer, actions as in section 10 of this document must be taken if the temperature recording is out of range.

- A record book for deliveries, recording date and time received, batch numbers and expiry dates should be kept for each designated vaccine refrigerator.

- An example of a record form can be found in Appendix 1. It is suggested that a separate form be used for each drug and kept in a ring binder near the refrigerator. It is also suggested that a copy of the manufacturers' instructions are kept with the record form for reference in the event of refrigerator failure/interruption of cold chain.

8. Defrosting and cleaning refrigerators

When defrosting or cleaning the refrigerator, vaccines must be transferred to a second refrigerator. This temporary storage refrigerator must also be monitored to ensure the correct temperature (2^{o}C to 8^{o}C) is maintained. Alternatively, store the vaccines in a pre-cooled insulated container with icepacks. Continue to monitor the temperature inside the container until the usual vaccine refrigerator is ready for use again (refer to The Green Book for detailed information)

9. Home visits and transportation of vaccines to outlying practices

Domestic cool boxes must not be used to store, distribute or transport vaccines. Validated cool boxes and ice packs from a recognised medical supply company must be used and must be

appropriate for the purpose required. Individual manufacturers' instructions should be strictly adhered to.

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 recommended by the manufacturers' instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage, such as being frozen.

10. Refrigerator failure or disruption of the cold chain

Arrangements should be in place for back up facilities to be available in the event of the refrigerator failing or breaking down.
Advice on suppliers of refrigeration equipment and accessories, such as cool boxes, is available from:

Immunisation Policy, Monitoring and Surveillance
Department of Health
Area 512, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel 020 7972 1227

If vaccine is exposed to temperatures outside the recommended storage range, the following procedure is suggested:

In general, any vaccine that has been exposed to temperatures outside the recommended storage range should not be administered.

- The vaccine manufacturer or ECCH pharmacist should be contacted and the following information provided:
    - Length of time the refrigerator has been off/malfunctioning
    - Current internal temperature of the refrigerator
    - Minimum and maximum temperature during last 24 hours (temperature records should be made at least daily)
    - Previous minimum and maximum temperatures
    - Type of vaccine product, date of expiry and batch numbers

- Discard any stock as advised by manufacturer/pharmacist

- Return salvageable products to cold chain immediately and:
    - Mark each product with date of break in cold chain and USE FIRST (and within the time scale suggested by manufacturer or ECCH pharmacist)
    - Mark each product with the new expiry date as advised by manufacturer or ECCH Pharmacist

- Inform the practice manager/ department manager who should:
    - Complete critical incident procedure to allow risk analysis
    - Check insurance policy covers for loss of stock

If an individual has inadvertently received a vaccine that is subsequently found to have been exposed to temperatures outside the recommended storage range, or if the vaccine is found to have passed its expiry date, advice should be sought on an individual basis from the vaccine manufacturer or ECCH Pharmacist or HPA Consultant in Communicable Disease Control (CCDC).

11. Further useful advice can be obtained from the following websites:

www.dh.gov.uk/greenbook Department of Health web based version of The Green Book 'Immunisation Against Infectious Disease'

www.dh.gov.uk Department of Health publications, policy and guidance

www.rpsgb.org.uk/ Royal Pharmaceutical Society of Great Britain

www.immunisation.org.uk NHS Health Promotion England

www.who.org World Health Organisation. Lists vaccination schedules for individual countries

www.dh.gov.uk/mmr Department of Health MMR website

www.dh.gov.uk/bcg Department of Health BCG website

www.ukph.org 'Starting Point' knowledge resource for UK Public Health Professional

www.emc.medicines.org.uk Summary of Product Characteristics (SPCs) and Patient Information Leaflets (PILs)

12. Standard Operating Procedures for the safe handling of heat-sensitive pharmaceuticals

See Appendix 2

13. References

The Green Book Immunisation Against Infectious Disease' 2006, Department of Health
Updated chapters can be found on the DH website www.dh.gov.uk/greenbook

Royal Pharmaceutical Society of Great Britain www.rpsgb.org.uk/

Department of Health (2008) The Health and Social Care Act. DoH London

14. Author

Infection Prevention and Control Team

APPENDIX 1

VACCINE DELIVERY/ REFRIGERATION RECORD

DRUG NAME:

QUANTITY	BATCH NUMBER(S)	EXPIRY DATE	DATE OF DELIVERY	TIME OF DELIVERY	TIME OF REFRIGERATION	INITIALS

Suggested Standard Operating Procedures for the safe handling of heat-sensitive pharmaceuticals

Stages of the process

Receipt of heat-sensitive products			
	Responsible	**Risks Associated**	**Audit**
1. Check stock against order form **as soon as order arrives**		Stock errors not identified. Cold chain broken.	
2. Check expiry date		Short dated/out of date stock not identified.	
3. Obtain keys to refrigerator from authorised key-holder			
4. Place stock in refrigerator (or freezer compartment if required) **immediately**, lock fridge and return keys		Cold chain broken.	

Action points	**By Who and by when**

Monitoring and maintenance of refrigerator			
	Responsible	**Risks Associated**	**Audit**
1. Refrigerator equipped with a minimum/maximum thermometer		Unable to monitor temperature.	
2. Min & Max temperature noted and recorded daily. Record date, time and initials		Unable to identify temperature problems. Cannot demonstrate compliance.	
3. If temperature outside 2-8^{o}C appropriate procedure followed*		Pharmaceuticals denatured. Risk of treatment failure or adverse effect.	
4. **Ensure fridge NOT overstocked and NO food or drink present**		Inappropriate temperature. Cross contamination	
5. Where a freezer present defrost ONCE a month		Inefficient functioning of fridge	

Action points	**By Who and by when**

*Fridge temperature outside 2-8^{o}C procedure

1. Check when temperature last recorded within normal range.
2. If less than 24 hours and fridge not more than 10^{o}C reset min/max thermometer, ensure fridge door has not been left open and fridge is not overstocked, and check again within 6 hours. If still above range then contact one of the ECCH pharmacists.
3. If below 2^{o}C or above 10^{o}C contact ECCH pharmacist
4. IN ALL INSTANCES WHERE FRIDGE TEMPERATURE OUTSIDE RANGE quarantine stock until have spoken to a ECCH pharmacist.
5. Document action required by ECCH pharmacist.