

Dr Jim Livingstone
Director of Safety, Quality and Standards



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poistie, Resydènter Heisin
an Fowk Siccar**

Rapid Response Report

Subject:

Vaccine Cold Storage

For action by:

Chief Executives, HSC Trusts for cascade to:

- *Directors of Pharmacy*
- *Medical Directors*
- *Directors of Nursing*
- *CSCG leads*

Chief Executive, HSC Board

Director of Commissioning, HSC Board for cascade to

- *Pharmacy & Medicines Management Team*

Chief Executive RQIA for cascade to:

- *Independent hospitals and clinics*

Family Practitioner Service Leads, Health & Social Care Board
(for cascade to General Medical Practitioners and Out of Hours
services)

Community Pharmacists

For Information to:

Chief Executive, Public Health Agency

Director of Public Health, Public Health Agency

Director of Nursing, Public Health Agency

Director of Performance Management & Service Improvement, HSCB

Director of Integrated Primary Care Services HSCB

Assistant Director of Performance Management, HSC Board

Assistant Director, Primary Care, HSCB

Professor David Woolfson, Head of School of Pharmacy, QUB

Professor Linda Johnston, Head of Nursing & Midwifery, QUB

Professor Hugh McKenna, Head of Life & Health Sciences, UU

Dr Owen Barr, Head of School of Nursing, UU

Professor Paul McCarron, Head of School of Pharmacy, UU

Post Graduate Dean, NIMDTA

Staff Tutor of Nursing, Open University

Director, Safety Forum

Lead, NI Medicines Governance Team

NI Medicines Information Service

NI Centre for Pharmacy Learning and Development

Summary of Contents:

The purpose of this circular is to improve the safety of vaccine storage.

Enquiries:

Any enquiries about the content of this Circular should be addressed to:

Safety & Quality Unit

DHSSPS

Room D2.4

Castle Buildings

Stormont

BELFAST

BT4 3SQ

Tel: 028 9052 2239

qualityandsafety@dhsspsni.gov.uk

Circular Reference: HSC (SQSD)01/10

Date of Issue: 1 March 2010

Related documents

Superseded documents

N/A

Status of Contents:

For completion of actions and assurance templates by 1 September 2010

Implementation:

Immediate

SQSD material can be accessed on:

<http://www.dhsspsni.gov.uk/index/phealth/sqs.htm>

Working for a Healthier People

Chief Medical Officer Group



Dear colleagues

VACCINE COLD STORAGE

Immunisation is a highly effective way of protecting individuals and communities from infectious disease. However, to remain potent, vaccines must be stored within the temperature range recommended by manufacturers [+2C to +8C]. Incorrect storage of vaccines is not only wasteful and costly; the failure to store vaccines correctly, particularly at temperatures **below** the manufacturer's recommendations, can reduce vaccine effectiveness and cause vaccine failures.

The content of the attached circular at Annex A has been reviewed by relevant professional colleagues in the Department and approved for regional dissemination.

I would ask you to bring this to the attention of relevant practitioners and key health and social care staff within your organisation. They should consider the best practice for their setting and take appropriate steps to minimise the risks to patients.

I would also draw your attention to the attached 'assurance template' which is a means of recording the response from the Trusts and Board in circumstances where SQS Circulars require action to be taken by a given date.

Yours sincerely



Dr J F Livingstone
Director, Safety, Quality & Standards

VACCINE COLD STORAGE

Issue

1. Immunisation is a highly effective way of protecting individuals and communities from infectious disease. However, to remain potent, vaccines must be stored within the temperature range recommended by manufacturers [+2C to +8C]. Incorrect storage of vaccines is not only wasteful and costly; the failure to store vaccines correctly, particularly at temperatures **below** the manufacturer's recommendations, can reduce vaccine effectiveness and cause vaccine failures. Freezing may also cause hairline cracks in the container, leading to contamination of the contents.

National Context

2. The National Patient Safety Agency (NPSA) has reported that between January 2005 and April 2009, about 50 million doses of childhood vaccines were distributed in the UK. During this period it received 260 reports of incidents from a range of NHS organisations related to vaccination cold storage. Themes identified from these reports include: delay in storage of vaccines (especially after delivery); storage at wrong temperature; fridge switched off or broken; power cut or fridge door left open; no temperature monitoring; inadequate or missing equipment; and inappropriate use of domestic fridges. It is unknown if any of these incidents led to significant harm.

NPSA/2009/RRR008: Vaccine Cold Storage is available on:
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=66111>

Local Context

3. All HSC organisations and independent sector organisations whose departments and providers (including independent contractors) hold vaccines requiring cold storage should:
 - Ensure that all departments and providers (including independent contractors) holding vaccine stocks are aware of relevant policy on safe storage. Local policies should include having a designated person and deputy/ies responsible for receipt and storage of vaccines.
 - Have procedures in place to assure themselves that all relevant departments and providers adhere to relevant policies for vaccine cold chain storage. This includes reviewing refrigerator temperature readings in a manner that will identify if vaccines have been stored outside of manufacturers recommended temperature ranges before they are administered to patients.

- Have procedures in place for remedial action where vaccines are stored outside manufacturers recommended temperature ranges, and ensure departments and providers are aware of these. Actions may include initial reference to the UKMi fridge database www.ukmi.nhs.uk/applications/fridge), which provides practical day-to-day guidance on the use of UK-licensed medicines and vaccines when the cold chain has been broken, and maintains a database that collates published and unpublished information from manufacturers, with subsequent advice sought from Northern Ireland Medicines Information Services or the vaccine manufacturer.

Action Required

4. You will wish to bring the contents of this document to the attention of staff, particularly those involved in governance and risk management within your organisation. Organisations need to be aware of this best practice circular in order to assist in complying with the Quality Standards for Health and Social Care –
 - Criteria 4.3(i) (the appropriate management of risk);
 - Criterion 5.3.1(f)(viii) (ensuring safe practice in medicines management); and
 - Criterion 5.3.3(f) (implementation of evidence-based practice through guidance, for example, NPSA guidance).
5. HSC Trusts should take immediate action to implement this Rapid Response Report as outlined in paragraph 4 above by **1 September 2010**. Trusts should provide assurance on this action to the HSC Board by completing **Section 2** of the attached template.
6. The HSC Board should complete **Section 1** of the attached assurance template and forward to the Department by **1 October 2010**.

SQS CIRCULARS: ASSURANCE TEMPLATE FOR HSC BOARD AND TRUSTS

Circular number: HSC (SQSD) 01/10 Vaccine Cold Storage
For Implementation by: 01/09/2010

(Section 2 is to be completed by HSCT and forwarded to HSCB for consideration. Section 1 should then be completed by HSCB and forwarded to DHSSPS)

SECTION 1:

To: Director, Safety, Quality & Standards Directorate, DHSSPS

I note the response from the Trust and –

I can confirm that the HSC Board is content the action(s) taken referred to in Section 2 below, complies with the requirements of the above circular.

I can confirm that the HSC Board is monitoring compliance with the above circular and has requested that further action is taken as follows:

I confirm that the Chief Executive and designated senior manager have been advised of this response and are content that it should be submitted to the Department.

Response submitted by: _____ (Name & contact details of person submitting response) on behalf of HSC Board. Date: _____

SECTION 2:

To: Chief Executive, HSC Board

I can confirm that the required actions set out in the above circular have been implemented in full by the due date.

I can confirm that the actions in the above correspondence have been partially implemented by the due date. Work is ongoing in the following areas:

I can confirm that the organisation has been unable to implement any actions of the above circular for the following reasons:

I confirm that the Chief Executive and designated senior manager have been advised of this response and are content that it should be submitted to the HSC Board.

Response submitted by: _____ (Name & contact details of person submitting response) on behalf of _____ HSC Trust. Date: _____