

**Dr Jim Livingstone**  
Director of Safety, Quality and Standards



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

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

AN ROINN  
**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O  
**Poustie, Resydènter Heisin  
an Fowk Siccar**

## **Patient Safety Alert**

### **Subject:**

**Safer spinal (intrathecal), epidural and regional devices**

### **For action by:**

Chief Executive, HSC Board  
Director of Commissioning, HSC Board  
Assistant Director of Pharmacy & Medicine Management, HSCB  
Chief Executives, HSC Trusts for cascade to:

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

Chief Executive RQIA for cascade to:

- *Independent hospitals and clinics*

Clinical Director, NI Cancer Centre  
Chief Executive, Business Services Organisation

### **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
- Assistant Director of Performance Management, 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 highlight the importance of safer spinal (intrathecal), epidural and regional devices

### **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](mailto:qualityandsafety@dhsspsni.gov.uk)

**Circular Reference: HSC (SQSD) 85/09**

**Date of Issue: 14 January 2010**

### **Related documents**

[HSC \(SQSD\) 28/07 NPSA Safe Medication Alerts](#)

[HSC \(SQSD\) 28/07 Safer Practice with Epidural Injections and Infusions Addendum 01/08](#)

[HSC \(SQSD\) 28/07 Safer Practice with Epidural Injections and Infusions Addendum 02/08](#)

[HSC \(SQSD\) 28/07 Safer Practice with Epidural Injections and Infusions Addendum 03/08](#)

[Recommendations for implementation in Northern Ireland](#)

[HSC \(SQSD\) 61/08 Using Vinca Alkaloid Minibags](#)

### **Superseded documents**

N/A

### **Status of Contents:**

For completion of actions and assurance templates  
**Part A by 1 April 2011; and Part B by 1 April 2013**

### **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

### **Safer spinal (intrathecal), epidural and regional devices**

The National Patient Safety Agency (NPSA) has reported that there have been fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route, and where epidural medicines have been administered by the intravenous (vein) route. There is also the potential for medicines intended for regional anaesthesia to be administered by the intravenous route, with fatal outcomes.

Wrong route errors will always be possible as long as medical devices with standard (Luer) connectors are used. The introduction and use of medical devices which do not physically connect with intravenous equipment will further reduce the risk of wrong route errors.

NPSA/2009/PSA004: *Safer spinal (intrathecal), epidural and regional devices* is available on <http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=65259>

The content of the attached circular at Annex A has been reviewed by relevant professional colleagues in the Department and approved for regional dissemination. It sets out **two** timescales for implementation:

- From 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with connectors that **will not** connect with intravenous Luer connectors (Part A)
- From 1 April 2013 all epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that **will not** connect with intravenous Luer connectors or intravenous infusion spikes (Part B)

It is recognised that devices with safer connectors are not currently available. The 2011 deadline is, therefore, intended to allow sufficient time for the medical device and pharmaceutical industry to develop new devices that will facilitate safer practice. **In the meantime it is recommended that HSC organisations and the independent sector work together with HSC Business Services Organisation (BSO) in the development of a regional approach to the procurement of these devices.**

HSC organisations should review and update clinical procedures and protocols and provide relevant training in the use of these devices in line with their procurement strategy to ensure that there is a regional approach to the implementation of these devices within the target timescales.

I would ask you to bring this circular 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 further minimise the risks to patients.

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

Yours sincerely

A handwritten signature in black ink, appearing to read "Jim Livingstone". The signature is written in a cursive, slightly slanted style.

**Dr J F Livingstone**  
Director, Safety, Quality & Standards

## **SAFER SPINAL (INTRATHECAL), EPIDURAL AND REGIONAL DEVICES**

### **Issue**

1. There have been fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route and epidural medicines that have been administered by the intravenous (vein) route. There is also the potential for medicines intended for regional anaesthesia to be administered by the intravenous route, with fatal outcomes.
2. These wrong route errors will always be possible as long as medical devices with standard (Luer) connectors are used. The introduction and use of medical devices which do not physically connect with intravenous equipment will further reduce the risk of wrong route errors.

### **National Context**

3. The last reported fatal wrong route incident involving epidural medicine was in February 2007. A further 18 low or no harm reports of wrong route errors involving epidural procedures and four involving regional anaesthesia procedures have been reported between 1 January 2008 and 31 July 2009. There have been no further reports of intravenous vinca alkaloids being administered by the spinal route in the UK, but additional deaths have occurred in other countries.
4. The introduction of devices with safer connectors does not replace previous safe practice guidance on intrathecal chemotherapy and epidural therapy, but rather is intended to further minimise risks to patients.

### **Local Context**

5. HSC organisations and the independent sector should review and update their purchasing policies, procedures and clinical protocols to ensure that:

#### **By 1 April 2011**

- i. all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that will not connect with intravenous Luer connectors;
- ii. medical device and pharmaceutical manufacturers supply devices with safer connectors well before the required implementation date, to enable clinical evaluation and changes in the supply chain to occur;

- iii. new orders for non-compliant devices should not be requested six months before the required implementation date to enable time for clinical evaluation and changes in the supply chain.

### **By 1 April 2013**

- i. all epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes;
- ii. medical device and pharmaceutical manufacturers supply devices with safer connectors well before the required implementation date, to enable clinical evaluation and changes in the supply chain to occur;
- iii. new orders for non-compliant devices should not be requested six months before the required implementation date to enable time for clinical evaluation and changes in the supply chain.

### **Action Required**

6. You will wish to bring the contents of this circular to the attention of staff, particularly those involved in governance and risk management within your organisation. Organisations need to be aware of this Patient Safety Alert 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) and (ix) (ensuring safe practice in medicines management, particularly in areas of high risk such as intrathecal chemotherapy); and
  - Criterion 5.3.3(f) (implementation of evidence-based practice through guidance, for example, NPSA guidance).
7. HSC Trusts should take action to implement the recommendations outlined in the paragraphs above and provide assurances on actions to **Part A by 1 April 2011** and **Part B by 1 April 2013**. **Section 2** of the attached assurance template should be completed and forwarded to the HSC Board within the required timescales.
8. The HSC Board should complete **Section 1** of the attached assurance template and forward to the Department by **29 April 2011** and **29 April 2013** respectively.

## **SQS CIRCULARS: ASSURANCE TEMPLATE FOR HSC TRUSTS**

### **HSC (SQSD) 85/2009      Part A for Implementation by: 1 April 2011**

(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)

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#### **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: \_\_\_\_\_

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#### **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: \_\_\_\_\_

**SQS CIRCULARS: ASSURANCE TEMPLATE FOR HSC TRUSTS**

**HSC (SQSD) 85/2009      Part B for Implementation by: 1 April 2013**

**(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)**

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**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: \_\_\_\_\_

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**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: \_\_\_\_\_