



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
- Paul Cunningham, HSCB
- Sam Blackley, Head of Regional Procurement, BSO
- Professor David Woolfson, Head of School of Pharmacy, QUB
- Professor Linda Johnston, Head of Nursing & Midwifery, QUB
- Professor Patrick Johnston, Dean, School of Medicine, 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
- NI Medicines Information Service
- NI Centre for Pharmacy Learning and Development

Summary of Contents:

The purpose of this circular is update the implementation date of circular HSC (SQSD) 85/09 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

Related documents

HSC (SQSD) 85/09 Safer spinal, epidural & regional devices

<http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-circulars/sqsd-circulars-2009-2010.htm>

Superseded documents

N/A

Status of Contents:

For completion of actions and assurance templates
Part A by 1 April 2012; and Part B by 1 April 2013

Implementation:

Immediate

SQSD material can be accessed on:

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



Dear colleagues

Safer spinal (intrathecal), epidural and regional devices

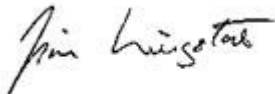
NPSA issued NPSA/2009/PSA004, parts A & B, in November 2009. HSC (SQSD) 85/09 was subsequently issued by the Department in January 2010.

NPSA has now issued guidance to replace NPSA/2009/PSA004A which changes the alert implementation date from 1 April 2011 to 1 April 2012 and updates the list of actions. Part B of the Alert (NPSA/2009/PSA004B) remains unchanged and no further changes to the implementation target dates are anticipated.

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.
3. It is recognised that a full range of such devices are not currently available in the UK. By issuing this circular the HSC wishes to clearly indicate to the medical device and pharmaceutical industry, the service's intention to purchase products that facilitate safer practice. The two dates included in this guidance provide sufficient time for the industry to develop new products.
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

National Context

5. NPSA issued NPSA/2009/PSA004, parts A & B, in November 2009. They have now issued NPSA/2011/PSA001 to update the implementation date of NPSA/2009/PSA004A from 1st April 2011 to 1st April 2012. This will provide healthcare organisations with additional time to review and evaluate the range of new devices and test information available, introduce these new devices into practice and take action required to minimise any new risks associated with the introduction of these devices. NPSA/2009/PSA004B remains unchanged.
6. NPSA/2011/PSA 001: Safer spinal (intrathecal), epidural and regional devices is available on: <http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=94529>

The NPSA has produced a Neuraxial Update newsletter providing contact details of device suppliers and other information. This newsletter is available at: <http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=94529>

Local Context

7. HSC organisations and the independent sector should continue to work together with HSC Business Services Organisation (BSO) in the development of a regional approach to the procurement of these devices.
8. HSC organisations and the independent sector should review and update their purchasing policies, procedures and clinical protocols to ensure that:

By 1 April 2012

- 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. in order to achieve this the range of new devices and test information should be evaluated locally and actions taken to minimise any new risks associated with the introduction of these devices;
- iii. safer devices are introduced into practice as soon as possible and without undue delay during 2011 in order to comply with the implementation deadline of 1st April 2012;
- iv. continued use of any non-compliant devices, after the deadline should be entered into the organisation's risk register, additional safety precautions taken and suitable safer devices introduced into practice as soon as they are available
- v. 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;
- vi. 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

9. 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), (ix) and (x) (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).
10. HSC Trusts should take action to implement the recommendations outlined in paragraph 8 above and provide assurances on actions to **Part A by 1 April 2012** and **Part B by 1 April 2013** respectively. **Section 1** of the attached assurance template should be completed and forwarded to the HSC Board within the required timescales.
11. The HSC Board should complete **Section 2** of the attached assurance template and forward to the Department by **29 April 2012** and **29 April 2013** respectively.

SQS CIRCULARS: ASSURANCE TEMPLATE FOR HSC BOARD AND TRUSTS

HSC (SQSD) 85/2009 Addendum 1 Part A for Implementation by: 1 April 2012

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

SECTION 1:

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. The issues impacting on full implementation along with the timescales for resolving these issues are set out in the box below:

I can confirm that the organisation has been unable to implement any actions of the above circular for the reasons set out in the box below. (The actions being taken/required to resolve or clarify the issues preventing implementation and the timescales for this should be outlined):

I confirm that the HSC Trust's 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: _____

SECTION 2:

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 1, complies with the requirements of the above circular.

I can confirm that further action, as outlined in the box below, is needed to ensure compliance with the requirements of the above circular

I confirm that the HSC Board's 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: _____

SQS CIRCULARS: ASSURANCE TEMPLATE FOR HSC BOARD AND TRUSTS

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

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

SECTION 1:

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. The issues impacting on full implementation along with the timescales for resolving these issues are set out in the box below:

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