National Patient Safety Agency

National Reporting and Learning Service

Patient Safety Alerts NPSA/2009/PSA004A and NPSA/2009/PSA004B

Safer spinal (intrathecal), epidural and regional devices – Part A and Part B

November 2009

Supporting information

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NOTE: This supporting information is intended to be read with the Patient Safety Alert (Part A and Part B) at www.nrls.npsa.nhs.uk/alerts

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1. Further details of the actions recommended

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a purchasing for safety initiative to ensure that:

Part A

By 1 April 2011

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.

Part B

By 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.

Medical device and pharmaceutical manufacturers should supply devices with safer connectors well before the required implementation dates, to enable clinical evaluation and changes in the supply chain to occur.

The NHS should not request further orders for non-compliant devices six months before the implementation dates.

Organisations should signal their compliance status on 1 April 2011 and 1 April 2013 to the Department of Health (DH) in England (using the Central Alerting System) or the Welsh Assembly Government in Wales.

1.1 Definition of specified devices

Devices are used to:

(a) Administer ‘spinal’ medications (e.g. intrathecal chemotherapy, anaesthetics, radiological contrast agents, antibiotics and analgesics) via the intrathecal space including the ventricles of the brain. The terms ‘spinal’, ‘subarachnoid’ and ‘intrathecal’ are equivalent and describe the fluid filled space surrounding the spinal cord and brain.
(b) Administer epidural medicines (e.g. anaesthetics) into the epidural space (also known as the extradural or peridural space) which lies outside the subarachnoid space.

(c) Either measure the pressure of, or remove, cerebro-spinal fluid from the subarachnoid space for diagnostic or therapeutic purposes.
(d) Administer regional infusions (e.g. anaesthetics) affecting a large part of the body, such as a limb, and includes plexus blocks such as brachial plexus blocks and single nerve blocks. For the purpose of this guidance it will also include the continuous infusion of wounds with local anaesthetic agents.

Local anaesthesia is anaesthesia of a small part of the body, such as a tooth or a small area of skin, and devices for this form of anaesthesia are not included in this guidance.

1.2 In order to achieve the above, organisations are recommended to take the following steps by the set implementation date:

Plan

1. Identify medical devices affected by these recommendations and the clinical areas using them.
2. Seek assurance from the product suppliers that compliant equipment will be available well in advance of implementation dates, and if not, identify alternative suppliers. Provide information on the number of new devices required to suppliers, NHS Supply Chain or Welsh Health Supplies who will assist with this change.
3. Involve clinical users in the selection and evaluation of the new devices.
4. Communicate with staff concerning the changeover programme.

Do

5. Review and, where necessary, modify clinical storage areas to accommodate the new devices.
6. Make available stocks of the specified devices with safer connectors in appropriate clinical areas and remove stocks of devices that do not comply with NPSA recommendations. Organise easily accessible backup and emergency supplies of these devices that are available at all times.
7. Eliminate the use of three-way taps and adaptors with Luer connectors, which enable connection of specified devices to intravenous devices.
8. Supply, where possible, medicines for spinal (intrathecal), epidural and regional administration to clinical areas in a ready to administer form in medical devices with safer connectors.

Review

9. Review and update organisational policies, procedures and clinical protocols to include the use of specified devices with safer connectors.
10. Include the use of specified devices with safer connectors as part of the organisations training and competency assessment programmes.
11. Add to the organisation's risk register any use of non-compliant devices after the required implementation dates. Introduce additional local safeguards and seek to purchase compliant devices as soon as they become available.
12. Audit the implementation of specified devices with safer connectors and monitor patient safety incident reports, including any arising following the introduction of new devices. Inform organisation governance and risk management groups of the results of audit and incident review at least annually.

1.3 Labelling specified devices and medicines

Currently, there is no international standard for labels on spinal (intrathecal), epidural or regional devices. The NPSA is recommending that standard-setting organisations develop such a standard that uses colour and design to help differentiate these types of devices from others used for intravenous and other uses.

Until formally recognised standards are developed, healthcare organisations should ensure that all specified devices and medicines used with these devices are clearly labelled to indicate their use, **e.g. for spinal (intrathecal), epidural/regional use only.** The term 'neuraxial' is not clearly understood by all healthcare staff and is not recommended to be used.

The use of the colour yellow is widely used by healthcare manufacturers and practitioners on labels and devices to help reinforce that these products are for a specified route and not for intravenous use.

1.4 Additional costs of devices with safer connectors

The costs of devices with safer connectors may be more than the costs of existing devices. As new devices are placed on the market, the NPSA, working with NHS Supply Chain and Welsh Health Supplies, will collate the costs of the new devices and communicate this information to both healthcare commissioners and service providers to enable cost-effective purchasing and financial planning.

2. Background

2.1 Universal use of the Luer connector and previous guidance

The Luer connector design has been used in medical devices for a wide variety of medical applications, including intravenous, hypodermic, spinal (intrathecal), epidural, enteral, medical gas and blood pressure monitoring systems. The wide use of the Luer connector design enables wrong route patient safety incidents to occur. In addition, the same design 'spike' connector is used to connect infusions to administration sets for a range of routes.

In the UK, intravenous medicines have been administered by the spinal (intrathecal) route and epidural medicines have been administered by the intravenous route causing fatal patient safety incidents. The DH has issued guidance concerning the safe use of intrathecal chemotherapy[1,2,3], and the NPSA has issued guidance on the safe use of epidural medicines[4].

However, mis-connection and wrong route errors continue to be reported to the NPSA and are physically possible as long as medical devices with common Luer connectors and infusion spikes are purchased for spinal (intrathecal), epidural and regional use.

In 2007 the NPSA issued a purchasing for safety initiative to minimise the use of oral and enteral devices with standard configuration Luer connectors in the NHS[5]. This initiative has been very effective in minimising the risks of wrong route incidents with oral liquid medicines, feeds and flushes.

The NPSA is recommending a similar initiative concerning the purchase of spinal (intrathecal), epidural and regional devices. The initiative is designed to increase the use of devices with safer connectors and further minimise the risk of wrong route incidents. It is recognised that a full range of such devices are not currently available in the UK. By issuing this Alert the NHS 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 provides sufficient time for the industry to develop new products and for NHS organisations to plan their implementation of these devices.

2.2 The development, trial and evaluation of a safe connector design for spinal, epidural and regional use

Following incidents of death or paralysis as a result of mal-administered intravenous vincristine by the spinal (intrathecal) route, the elimination of harm from this cause was one of the four specific targets in the DH Report *An Organisation with a Memory* (2000)[6].

The publication of two reports relating to the prevention of intrathecal medication errors in 2001[7,8] led the DH to issue national guidance for safe administration of intrathecal chemotherapy[1.2.3].

At the same time, the DH established a project to oversee the development, trial and evaluation of a non-Luer connector design to further reduce the risk of wrong route errors with spinal (intrathecal) and epidural medical devices. An advertisement for a non-Luer connector design to be fitted to spinal (intrathecal) devices was placed in the *Official Journal of the European Communities* (OJEC) in 2002.

The NPSA published a risk assessment of different device design options in 2004[9]. This report recommended that the design solution incorporating a non-Luer compliant connector should be used for all spinal (intrathecal) and epidural procedures in all clinical settings, as this was the most appropriate option to minimise patient safety risks. The NPSA report recommended that pilot studies should be undertaken to test the new devices in practice.

In 2006 the NHS Patient Safety Research Portfolio commissioned the following research:

1. A prospective hazard analysis of introducing non-Luer connectors for spinal (intrathecal) injections[10].
2. Evaluation of prototypes to establish ‘usability’ within a non-clinical ‘simulation’ environment[11].
3. Evaluation of prototypes to establish ‘usability’ when used with patients in clinical practice in hospital practice settings[12].

Three prototypes were examined, but only one successfully completed laboratory, simulation and clinical assessment stages, and was found to meet the functional specification.

The results of the DH initiative to develop trial and evaluate a new non-Luer connector for spinal (intrathecal) and epidural demonstrated that such a design could be developed and used in devices to treat patients. Further refinement of this connector design and other designs and their inclusion in a range of spinal (intrathecal), epidural and regional devices is required. The NPSA Alert is being issued now to prompt that safer connector designs are further defined and incorporated in the range of products used by the NHS.

User testing of all devices fitted with non-Luer connectors is essential before purchasing for safety decisions can be taken by the healthcare organisations.

Work is in progress to develop an International Organization for Standardization (ISO) industry standard for small bore (non-Luer) connectors for spinal (intrathecal) and epidural use, and a range of other medical devices (see section 2.4).

The NPSA is recommending that actions be taken by the NHS and the independent sector to purchase spinal (intrathecal), epidural and regional devices with safer connectors within the stated time scale. This may be in advance of the new ISO international standard and subsequent modification of other device standards.

2.3 Purchasing for safety guidance internationally

This NPSA guidance concerning the use of spinal (intrathecal), epidural and regional devices with safer connectors is similar to that already issued by the Joint Commission[13] and the California State legislature[14] in the US.

The Food and Drugs Administration in the US has issued a Medical Devices Safety Calendar which provides a graphic depiction of misconnection cases that have occurred over a wide range of medical devices, including spinal (intrathecal) and epidural devices and recommendations on how to minimise these risks in the interim before devices with safer connectors become widely available[15].

2.4 The development of new industry standards

In 2000, a European Standards (CEN) Task Force recommended that Luer connectors be restricted to intravenous and hypodermic devices[16].

European standard EN 15546-1:2008 *Small bore connectors for liquids and gases in healthcare applications. Part 1 - General Requirements* was published in 2008[17]. The standard is intended to be a reference document that can be used as a tool to minimise the risk of misconnections of small bore connectors between different medical applications. It provides a framework to assess non-interchangeability of small bore connectors based on their inherent design and dimensions.

Work is underway to develop detailed new global standards for specific small bore connector applications via the ISO standards organisation TC210 Committee[18].

3. Patient safety incident reports

The NPSA issued Patient Safety Alert 21, *Safer Use of Epidural Medicine*s in March 2007, with an implementation date of December 2008[5].

A further 18 low or no harm reports of wrong route errors involving epidural devices and four involving regional devices 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 (intrathecal) route in the UK, but additional deaths have occurred in other countries.

Table 1. Number of patient safety incidents by wrong route incident type

Wrong route incident type	Number of incidents
Epidural medicine administered by the intravenous route	9
Intravenous medicine administered by the epidural route	9
Intravenous medicine administered by the regional anaesthetic route	3
Regional medicine administered by the intravenous route	1

3.1 Examples of incidents where epidural medicines were administered by the intravenous route:

(a) Epidural catheter connected to patient's intravenous infusion therapy; 46ml noted in epidural syringe.

(b) I went to discard the central line for a patient and noticed that his epidural infusion was connected to the central line. I reported the incident to staff that was in charge of the day shift.

3.2 Example of incidents where intravenous medicines were administered by the epidural route

(a) Neostigmine 2.5mg and glycopyrrolate 500mg put down epidural catheter, through filter at the end of procedure by mistake. No obvious immediate effects.

(b) A woman in labour who had epidural analgesia. She was also prescribed benzylpenicillin 1.5mg prophylactically. Prepared benzylpenicillin 1.5mg in 20ml of sodium chloride. The patient wanted a top-up for her epidural at this time. She was accidentally administered 10ml of the prepared antibiotic down the epidural catheter.

(c) I had the metaraminol syringe, as one of the side effects of giving a top-up epidural is hypotension. Metaraminol if given IV in small boluses is a treatment for hypotension as it is a vasoconstrictor. I injected 10ml of metaraminol down the epidural instead of 10ml of "fizzy lidocaine".

(d) Consultant anaesthetist picked up syringe thinking that it was bupivacaine and gave 2ml by the epidural route. Noticed mistake a minute later. It was in fact gentamicin. The incident occurred while positioning the patient on the table; this is the busiest time for the consultant anaesthetist during the procedure. Manufacturers contacted for advice. The consultant anaesthetist aspirated back on the epidural but got very little back. Underlying cause, working in theatre alone, happened whilst positioning the patient.

(e) A recent national audit of neuraxial blocks has also reported continued wrong route errors[19].

3.3 Example of incidents where intravenous medicines were administered by the regional route

Accidental use of wrong drug in regional nerve block. In an attempted fascia iliaca block 20ml of diluted metaraminol solution (10mg in 20ml sodium chloride 0.9%) were injected instead of 20 ml bupivacaine. There were no direct ill effects observed, no rise in blood pressure, no blanching of skin or vascular spasm during surgery.

On doing a femoral nerve block, 1–2mls (100-150mg) of flucloxacillin was injected by mistake into the nerve. Problem identified, bupivacaine then given 125mg in 30ml volume. Surgeon informed and will explain to patient later in the day.

I was doing a femoral block, and accidentally used midazolam instead of bupivacaine 0.5%. Midazolam 2mg was injected before I noticed the error. No adverse effect from drug observed at 2 hours post patient/consultant/sister informed.

3.4 Example of incidents where regional medicines was administered by the intravenous route

Post-thoracotomy, paravertebral infusion. Levobupivacaine prepared in recovery, but attached to peripheral intravenous cannula.

4. Compliance checklists

Organisations should use the checklist below to assess compliance. When all actions have been completed, the guidance can be considered to be fully implemented and 'action completed' to DH.

		Part A Alert	Part B Alert
Action number	**Description**	**Compliance with spinal (intrathecal) bolus and lumbar puncture devices 2011**	**Compliance with epidural, spinal (intrathecal) and regional infusion devices 2013**
1	All medical devices used in the organisation affected by these recommendations have been identified and listed.		
2	All clinical areas in the organisation using devices affected by these recommendations have been identified and listed		
3	Compliant devices have been purchased, or where no suitable compliant device is commercially available, the continued use of non-compliant devices is recorded in the organisations risk register, additional local safeguards are implemented and the procurement of compliant devices, when available, is planned.		
4	Written communication to staff informing them of details of changeover programme.		
5	Clinical storage areas reviewed and modified where necessary for new devices.		
6	Supplies of new devices have been supplied to all identified areas and old stock withdrawn. Arrangements for easy access to backup and emergency supplies are in place.		
7	In practice all devices are clearly labelled to indicate the intended route of administration.		
8	Three-way taps and adapters with Luer connectors for use with compliant devices are not available.		
9	Where possible a range of ready to administer products in devices with safer connectors have been made available to clinical areas.		
10	Policies, procedures and clinical protocols have been updated to include the use of devices with safer connectors.		
11	Use of devices with safer connectors have been included in training and competency assessment programmes.		
12	An audit of the implementation of the devices with safer connectors has be planned to be completed within 12 months of the implementation date.		

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