Alert

Patient Safety Alert

NPSA/2011/PSA001
31 January 2011

NHS
National Patient Safety Agency

Safer spinal (intrathecal), epidural and regional devices Part A: update

This Patient Safety Alert replaces **NPSA/2009/PSA004A** issued on 29 November 2009. This update is being issued to change the Alert implementation date from 1 April 2011 to 1 April 2012 and update the list of actions. Part B of the Alert (**NPSA/2009/PSA004B**) remains unchanged and no further changes to the implementation target dates for Part A and Part B guidance are anticipated.

By 1 April 2012 healthcare organisations should have **completed** actions to ensure that all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with connectors that **cannot** also connect with intravenous equipment.

The implementation date is being changed to 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 potential practice risks arising from the use of these new devices by healthcare practitioners.

The NPSA has produced two Neuraxial Update newsletters providing contact details of device suppliers and other information. These newsletters are available at www.nrls.npsa.nhs.uk/saferconnectors.

Central Alerting System (CAS) liaison officers in trusts in England should record 'Action not required' for NPSA/2009/PSA004A and note in the free text box that the original Alert has been superseded. The replacement Alert should be actioned as normal.

The issue

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.

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 reduce the risk of wrong route errors.

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.

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 by 1 April 2012 the following actions will have been completed:

- all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that cannot connect with intravenous Luer connectors;
- in order to achieve the above the range of new devices and test information should be evaluated locally and actions taken to minimise any potential practice risks arising from the use of these new devices;
- 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 1 April 2012;
- continued use of any noncompliant devices, after the deadline should be recorded in the organisation's risk register, with additional safety precautions taken and suitable safer devices introduced into practice as soon as they are available.

A recommended checklist for implementation is on the next page.

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Patient safety incidents
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.

Recommended checklist for implementation for NHS organisations:

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 in spinal (intrathecal), epidural and regional procedures, 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 organisation's 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.

Supporting information
Further information to support the implementation of this guidance is available at:
www.nrls.npsa.nhs.uk/alerts

Further queries
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