



## Patient Safety Alert

NPSA/2009/PSA004B

24 November 2009

**NHS**

National Patient  
Safety Agency

National Reporting  
and Learning Service

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

From 1 April 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses should be performed with devices with connectors that **will not** also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2013 implementation date.

These devices with safer connectors are not currently available. By issuing this Alert the NHS is stating clearly to the medical device and pharmaceutical industry that it will only buy products that facilitate safer practice. The 2013 deadline is intended to allow sufficient time for the industry to develop new devices.

### 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 further reduce the risk of wrong route errors.

### Other safeguards

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.

The National Patient Safety Agency (NPSA) has previously issued guidance in 2007 to minimise the risks of wrong route epidural incidents, and in 2008 on using minibags for intravenous doses of vinca alkaloids. The Department of Health in England has also issued guidance on intrathecal chemotherapy. However, wrong route incidents are still being reported.

## 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 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 supply devices with safer connectors well before the required implementation date, to enable clinical evaluation and changes in the supply chain to occur;
- 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.

A recommended checklist for implementation is on the next page.

**NOTE:** Guidance in this Part B Alert should be read in conjunction with the Part A Alert detailing actions on safer connectors for spinal bolus doses and lumbar puncture samples. The alert is being issued in two parts in order to allow two separate timescales for implementation.



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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, 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](http://www.nrls.npsa.nhs.uk/alerts)

## Further queries

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