

Patient safety alert



Alert

28 March 2007

Immediate action	<input type="checkbox"/>
Action	<input checked="" type="checkbox"/>
Update	<input type="checkbox"/>
Information request	<input type="checkbox"/>

Ref: NPSA/2007/21

Safer practice with epidural injections and infusions

The National Patient Safety Agency (NPSA) has identified actions that can make administering epidural injections and infusions safer.

Between 2000 and 2004, three patient deaths were reported following the administration of epidural bupivacaine infusions by the intravenous route.¹ A review of reports made to the NPSA between 1 January 2005 and 31 May 2006 reveals that there were 346 incidents reported that involved epidural injections and infusions.

Most of these resulted in no or low harm, and included six incidents where epidural medicines had been administered by the intravenous route. The others included wrong route errors where intravenous medicines had been administered by the epidural route and the wrong product selected, resulting in the wrong drug or dose being administered.

These incidents highlight a number of risks related to epidural injections and infusions, including how the medicines and devices are labelled, stored and used. Managing these risks successfully will make patient care safer.

Action for the NHS and the independent sector

The NPSA recommends all NHS and independent sector organisations in England and Wales take the following steps to minimise risk when administering epidural injections and infusions:

- 1 Clearly label infusion bags and syringes for epidural therapy (whether purchased commercially, manufactured by the hospital pharmacy or prepared in clinical areas) with **'For Epidural Use Only'** in a large font. Make judicious use of colour and design to differentiate these products from those for administration by intravenous and other routes.
- 2 Minimise the likelihood of confusion between different types and strengths of epidural injections and infusions:
 - a Rationalise the range of epidural injections and infusions available, and introduce procedures for preparing and administering these products. Undertake an annual audit to ensure epidural practices adhere to the agreed range of products and procedures.
 - b Maximise the use of ready-to-administer epidural infusions to help reduce the need for complex calculations and preparations.

For response by:

- All NHS and independent sector organisations in England and Wales

For action by:

- The chief pharmacist/pharmaceutical advisor should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/risk manager

The following groups must also be involved in implementation:

- Medical staff
- Pharmacy staff
- Nursing staff
- Midwifery staff
- Patient advice and liaison service staff in England
- Procurement managers
- Medical engineering staff

The NPSA has informed:

- Chief executives of acute trusts, primary care organisations, ambulance trusts, mental health trusts and local health boards in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- Healthcare Commission
- Healthcare Inspectorate Wales
- Medicines and Healthcare

- products Regulatory Agency
- NHS Purchasing and Supply Agency
- Business Services Centre (Wales)
- Welsh Health Supplies
- Royal colleges and societies
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- Independent Healthcare Forum
- Relevant education providers
- Independent Healthcare Advisory Services
- Commission for Social Care Inspection

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- 3 Reduce the risk of the wrong medicine being selected by storing epidural infusions in separate cupboards or refrigerators from those holding intravenous and other types of infusions.
- 4 Use clearly labelled epidural administration sets and catheters that distinguish them from those used for intravenous and other routes.
- 5 Use infusion pumps and syringe driver devices for epidural infusions that are easily distinguishable from those used for intravenous and other types of infusion.
- 6 Ensure all staff involved in epidural therapy have received adequate training, and have the necessary work competences to undertake their duties safely.

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 2 July 2007

Action plan to be agreed and actions started

Deadline (action complete): 31 December 2007

All actions to be completed

Further information about SABS can be found at:

www.info.doh.gov.uk/sar2/cmopatie.nsf

Scope

The procedural recommendations in this patient safety alert are for acute care (for both adults and children) involving epidural injections and infusions, epidural top-ups and patient-controlled epidural analgesia. The full recommendations are not intended for use in palliative care or for the specialist management of persistent non-cancer pain. However, some of the recommendations, such as how to label infusions, syringes, administration sets and infusion devices, are likely to also be appropriate in other areas of practice.

The aim of this patient safety alert is to raise awareness about the risks associated with epidural medicines and to identify action that can improve patient safety. This guidance complements the comprehensive guidance published by professional practice organisations in the report *Good practice in the management of continuous epidural analgesia in the hospital setting*.²

Further information on the action points

- 1 **Clearly label infusion bags and syringes for epidural therapy (whether purchased commercially, manufactured by the hospital pharmacy or prepared in clinical areas) with 'For Epidural Use Only' in a large font. Make judicious use of colour and design to differentiate these products from those for administration by intravenous and other routes.**

Currently, there are no international or national standards specifically for the labels on epidural medicines. The NPSA is recommending that standard-setting organisations develop such a standard that uses colour and design to help differentiate epidural medicines from similar products intended to be administered by other routes. However, until a formally recognised standard is developed, all NHS organisations are advised to adopt the NPSA's recommendation that all infusion bags and syringes for epidural therapy are labelled with '**For Epidural Use Only**'.



- 2 Minimise the likelihood of confusion between different types and strengths of epidural injections and infusions:**
 - a Rationalise the range of epidural injections and infusions available, and introduce procedures for preparing and administering these products. Undertake an annual audit to ensure epidural practices adhere to the agreed range of products and procedures.**

Range of epidural injections and infusions

Healthcare organisations' drugs and therapeutics committees should review and rationalise the range of epidural injections and infusions available for use, including all those purchased and prepared in clinical areas. This could reduce the risk of staff being confused and selecting the wrong product or strength.

Healthcare organisations' buying policies should aim to purchase products that are designed to minimise the risk of selecting the wrong product or confusing one product with another. For example, bupivacaine 0.1% and 0.125% epidural infusions are available as licensed infusions and are supplied in an infusion container designed not to be used for intravenous infusions.

The local anaesthetic agent bupivacaine can cause profound disturbance of cardiac rhythm and contractility, resistant to conventional resuscitation manoeuvres, if given as an overdose by any route of administration. Levobupivacaine (Chirocaine) and ropivacaine (Naropin) are alternative long-acting local anaesthetic products to bupivacaine that can be used in epidural infusions. There is evidence to suggest that these newer agents have less cardiotoxicity than bupivacaine, but there is continuing controversy over whether bupivacaine should be replaced by the new agents in practice.^{3,4} All local anaesthetic agents can produce cardiotoxicity by direct and indirect mechanisms derived from their inhibition of voltage-gated ion channels. Whichever local anaesthetic agent is selected, the NPSA's recommendations set out in this patient safety alert should be implemented.

Procedures for preparing and administering epidural injections and infusions

Drugs and therapeutics committees should also review procedures for preparing and administering epidural injections and infusions in clinical areas. The NPSA recommends that a second practitioner independently confirms that the correct product and line connection have been selected and prepared, and that the administration method is correct.

Audit of epidural practice

Healthcare organisations should audit the use of epidural injections and infusions as part of their annual medicines management audit. This should ensure that practice adheres to NPSA recommendations and local procedures. Audit results should be reviewed alongside local patient safety incident data concerning the use of epidural medicines. A template epidural audit form is available at www.npsa.nhs.uk/health/alerts

The Royal College of Anaesthetists is conducting a national anaesthesia audit of major complications of spinal and epidural anaesthesia from September 2006 for 12 months. The aim is to determine the number of complications arising from these therapies. The Royal College has asked to be sent cases of major complication every month. For further information contact Dr Tim Cook, Audit Lead, at tcook@coa.ac.uk or telephone him on 020 7092 1500.



b Maximise the use of ready-to-administer epidural infusions to help reduce the need for complex calculations and preparations.

Ready-to-administer licensed epidural infusions should always be selected, if they are available. When rationalising the range of epidural infusions, well-designed and evidence-based licensed medicines should be an important criteria for inclusion. It is hoped that the pharmaceutical industry will provide more licensed ready-to-administer epidural infusions in the future.

If a licensed infusion is not available, a ready-to-administer and unlicensed product that has been prepared in the hospital pharmacy or commercially should be selected if its presentation, packaging and labelling has been designed with safety in mind. Such a product is preferable to one that has been prepared in a clinical area.

Only when ready-to-administer licensed and unlicensed products are not available should epidural infusions be prepared in clinical areas.

3 Reduce the risk of the wrong medicine being selected by storing epidural infusions in separate cupboards or refrigerators from those holding intravenous and other types of infusions.

Healthcare organisations should review their medicines management procedures to make sure that epidural infusions are not being stored alongside intravenous infusions.

Epidural infusions containing controlled drugs may be stored in the standard controlled drugs cupboard providing intravenous infusions containing controlled drugs are not stored in the same cupboard.

Pharmacy supply procedures should make sure that the correct types of epidural infusions are issued to authorised clinical areas. The NPSA has received reports of epidural infusion bags being issued when pre-filled epidural syringes were requested. Pharmacy supply procedures should also make sure that the epidural infusions are delivered directly to the authorised epidural storage location in the clinical area, rather than being supplied and left with the general ward stock for clinical staff to put away.

4 Use clearly labelled epidural administration sets and catheters that distinguish them from those used for intravenous and other routes.

Identical or unlabelled infusion administration sets may be being used for both epidural and intravenous administration and can be connected to the wrong route of administration or to the wrong infusion bag or syringe.

Healthcare organisations' procedures for epidural infusions should include a requirement that all epidural administration sets be clearly labelled '**Epidural**' when in use. Administration sets connected to either infusion bags or syringes should be labelled in this way. The procedures should also state how epidural catheters should be labelled or identified to make sure that they are connected safely to the labelled epidural administration sets.

Where possible, the NPSA recommends using commercial epidural administration sets. These sets use labelling and design, usually a yellow line, to help differentiate this route of administration from intravenous and other routes.

As with epidural medicines, there is no international or national standard for labelling epidural administration sets or catheters. The NPSA is recommending that standard-setting organisations develop a standard for epidural administration sets.



5 Use infusion pumps and syringe driver devices for epidural infusions that are easily distinguishable from those used for intravenous and other types of infusion.

The label, colour and design of epidural infusion pumps and syringe drivers, and the infusions systems they are attached to, should clearly identify them.

Clearly identified epidural infusion devices should be used exclusively for the epidural route or, if not, the pump should be marked clearly and unambiguously that it is **'For Epidural Use Only'** when it is being used for that purpose.

The NPSA previously issued a safer practice notice concerning infusion devices that recommended actions to reduce the risk of patient safety incidents involving infusion devices.⁵ The actions included:

- standardising the range of infusion device types in use and, within each type, having agreed default configurations;
- investigating the benefits of a centralised library to cost-effectively provide infusion devices of the appropriate type.

The NPSA developed a toolkit that can help healthcare organisations review the quality of their existing device management system, as well as assess the potential for significant cost benefits. The toolkit and further information are available from:

www.supplychain.nhs.uk

In this patient safety alert, the NPSA is clarifying and updating recommended safer practice guidelines for epidural infusion devices. The default configuration for infusion devices for epidural infusions should ensure that the label, colour and design of devices clearly identifies these devices from those used for intravenous infusions. When making purchasing decisions for epidural infusion devices, these factors should be included in the equipment specifications.

6 Ensure all staff involved in epidural therapy have received adequate training, and have the necessary work competences to undertake their duties safely.

There should be formal training and regular updates for clinical staff responsible for prescribing, preparing, administering and monitoring epidural injections and infusions. Senior staff should supervise recently trained staff and make sure they have the necessary work competences to undertake their duties safely and effectively. There should also be additional training for staff when changes are made to protocols, medicine products or medical devices.

Strategies for avoiding error should be complemented by protocols to assist resuscitation in the event of an injection or infusion going wrong. Bupivacaine toxicity can occur in an overdose from the intended route or from migration of the epidural catheter intravenously, as well as from accidentally connecting and administering by the intravenous route. Staff should be trained on how to manage toxicity and use resuscitation protocol wherever bupivacaine is administered. There is some evidence that the use of lipid emulsion (Intralipid) is of benefit when bupivacaine-induced cardiac dysfunction is refractory to normal resuscitation manoeuvres.⁶⁻⁸

The *National infusion devices training programme* has been developed by the NHS Core Learning Unit and the NPSA. The programme helps healthcare staff gain competence and confidence in using infusion devices, leading to safer and more efficient use. The programme is available either face-to-face or through an e-learning package. To find out more go to **www.clpu.nhs.uk**



The cost of implementing the NPSA's recommendations

The cost of implementing these recommendations will vary depending on current local practice.

The cost of ready-to-administer epidural products is similar to the cost of preparing infusions in the clinical area when the cost of the time taken by clinical staff to prepare these infusions is taken into account.

Labelling costs for epidural medicines, devices and infusion pumps are negligible. Organisations should include the procurement of dedicated epidural medicine products and devices in their business planning process where appropriate.

Background

Research has been published on the risks of the wrong route, drug or dose occurring when administering epidural medicines.^{9,10} In 2004, the NPSA published a report recognising the risk of using the wrong route in epidural therapy.¹¹ The report reviewed spinal procedures with current safeguards and with proposed new connector designs.

The NPSA is working with the Department of Health, who are leading on the development of a new connector for spinal (including epidural) medical devices. It is anticipated that new medical devices, fitted with unique spinal connectors that cannot be connected to the intravenous or other routes, will be introduced in the UK. While these new devices are being developed, it is important to introduce measures that reduce the risk of error with epidural infusions.

A review of the NPSA's National Reporting and Learning System (NRLS) identified 346 reports of patient safety incidents involving epidural medicines received between 1 January 2005 and 31 May 2006. Tables 1 to 3 summarise these reports.

Table 1: Clinical outcome of epidural incidents reported to the NRLS from 1 January 2005 to 31 May 2006

Clinical outcome ¹²	No. of reports
Severe harm (permanent harm)	1
Moderate harm (significant, but not permanent, harm requiring increase in treatment)	7
Low harm (temporary harm requiring extra observation or minor treatment)	45
No harm	293
Total	346

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Table 2: Types of epidural incidents reported to the NRLS from 1 January 2005 to 31 May 2006

Type of incident	No. of reports
Wrong route (epidural medicine administered by IV/IM routes)	8
Wrong route (intravenous medicine administered by epidural route*)	12
Wrong epidural drug	36
Wrong epidural dose	23
Error with other drug therapy when patient on epidural therapy	81
Documentation error	49
Error with programming or operating the infusion pump	31
Omitted epidural therapy	21
Supply error	20
Expired epidural infusion used	13
Incorrect storage of epidural medicine	8
Other types of incident involving epidural medicines	44
Total	346

* The intravenous medicines that were administered down the epidural line during the incidents were: ephedrine, morphine, oxytocin, potassium chloride in glucose, potassium chloride in sodium chloride, ranitidine and rocuronium.

Table 3: Clinical areas reporting epidural incidents to the NRLS from 1 January 2005 to 31 May 2006

Clinical area	No. of reports
General surgery	76
Other surgical areas	67
Obstetrics	63
Trauma and orthopaedics	38
Anaesthetics	21
Gynaecology	15
Medicine	14
Other	52
Total	346



Further details

For further information about the NPSA's work on epidural injections and infusions, please contact:

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For more information about how you can improve patient safety, visit www.saferhealthcare.org.uk – one stop for knowledge and innovation for safer healthcare.

References

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- 9 Yentis SM, Randall K. Drug errors in obstetric anaesthesia: a national survey. *Int J Obstet Anesth*. 2003; 12: 246-249
- 10 Hew CM et al. Avoiding inadvertent epidural injection of drugs intended for non-epidural use. *Anesth Intensive Care*. 2003; 31: 44-49
- 11 National Patient Safety Agency. *Risk assessment of spinal procedures with current safeguards and with proposed new connector designs*. (2004). Available at: www.npsa.nhs.uk
- 12 National Patient Safety Agency. *Seven steps to patient safety: the full reference guide*. Available at: www.npsa.nhs.uk/sevensteps



A patient safety alert requires prompt action to address high risk safety problems.

This patient safety alert was written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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