National Patient Safety Agency (NPSA) Alert 21 – Safer practice with epidural injections and infusions

Recommendations for implementation in Northern Ireland
Updated August 2008

Introduction

Following the NPSA Alert 21, a multidisciplinary working group with representation from each of the five H&SC Trusts was convened to agree a regional approach and recommendations for local implementation of the alert for adults and children (Appendix 1).

These regional recommendations must be read in conjunction with NPSA alert 21.
http://www.npsa.nhs.uk/patientsafety/alerts-anddirectives/alerts/epidural-injections-and-infusions/

The group recommend that Trusts implement the attached by 30 June 2008:

Labelling

NPSA Recommendation 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 large font. These products should be clearly differentiated from those for administration by intravenous and other routes.

- Black text on yellow labels - 'For Epidural Use Only' should be used on epidural administration sets, delivery pumps and lockable boxes.
- All infusion bags must have yellow labels/black text – 'For Epidural Use Only' whether purchased commercially or manufactured by hospital pharmacy.
- Additive labels* for other routes of infusion, for example intravenous and subcutaneous infusions, must **not** be yellow in colour.
- Trusts must consider the use of another colour (ie grey) for labelling of other infusion systems for delivery of local anaesthetic drugs.

* Labels used as part of the International Colour Coding System for Syringe Labelling recommended by the Councils of the Royal College of Anaesthetists, the Association of Anaesthetists of Great Britain and Ireland, the Faculty of Accident and Emergency Medicine and the Intensive Care Society are not additive labels and are unaffected by this recommendation.

Ready to administer products

NPSA Recommendation 2: Minimise the likelihood of confusion between different types and strengths of epidural injections and infusions by rationalising the range of epidural products available, introducing procedures for preparation and administration (see training and competency section below) and maximising the use of ready to administer infusions.

Regional rationalisation of epidural products will maximise the use of ready to administer epidural infusions, reduce the need for complex calculations, and improve consistency, training and safety across Northern Ireland. It will also ensure effective partnership with NHS production units to meet product specifications and supply demands for Northern Ireland.

- The range of ready to administer epidurals used in NI should be rationalised to:

  Unlicensed products:
    - Levobupivacaine 0.1%/fentanyl 2 micrograms/ml in Sodium Chloride 0.9% (250ml)
    - Levobupivacaine 0.1%/fentanyl 2 micrograms/ml in Sodium Chloride 0.9% (100ml)
    - Levobupivacaine 0.1%/fentanyl 5 micrograms/ml in Sodium Chloride 0.9% (250ml)

  Licensed products:
    - Levobupivacaine 0.125% in 100ml or 200ml (licensed products from Abbott do not currently conform to labelling requirements at present)
    - Ropivacaine 2mg/ml 200ml infusion

Where a Trust is not currently using levobupivacaine for epidural infusions, a re-evaluation of the cost to switch to levobupivacaine should be conducted.

No additions are to be made to any ready to administer epidural infusion bag (commercially produced or made by pharmacy).

Where products other than those listed above are requested, this must be approved by the Trust Drug and Therapeutics Committee.

Trusts should risk assess any area where epidurals are prepared in the clinical area rather than using ready to administer products and ensure NPSA recommendation 1 is adhered to.

Safe storage

NPSA Recommendation 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.

- Trusts should review the requirement for and range of local anaesthetic injections and infusions to be held as ward stock (lidocaine, bupivacaine, levobupivacaine, prilocaine, ropivacaine).
- Trusts should ensure clinical areas have a separate, lockable cupboard for the storage of local anaesthetic drugs.
- Epidural infusions containing controlled drugs must be stored in a separate controlled drugs cabinet solely for that use.
- For use outside of the theatre environment, only levobupivacaine (2.5mg/ml, 5mg/ml) or ropivacaine (2mg/ml, 7.5mg/ml) ampoules should be available (when indicated for epidural use).
- Trusts should review procedures when patients receiving epidurals containing controlled drugs are transferred from one clinical area to another to ensure a clear audit trail of transfer of responsibility.

Administration

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

- Dedicated epidural administration sets, with anti-free flow safety mechanisms and a yellow line should be used to clearly identify an epidural in situ.

- The epidural administration set / catheter should be labelled with black text on a yellow label, clearly labelled 'For Epidural Use Only'.
- No extension sets should be used to administer epidurals.
- There should be a bacterial filter in situ at the junction of the epidural catheter and infusion line.
- Trusts should do a risk assessment to determine if patient identifiers are to be attached to the epidural infusions.

Recommendation 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.

- Only programmable epidural devices are to be used to deliver drugs by the epidural route. If this is not possible, Trusts must risk assess the infusion devices in use and ensure that they are 'dedicated' for epidural administration only. The pump must be marked clearly and unambiguously that it is 'For Epidural Use Only' (black text on a yellow label).
- Epidural devices should have programmable safety limits, software locks and allow the infusion bag to be enclosed in a lockable compartment.

Training and competency

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

- Trusts should develop mandatory training programmes and competency based assessments and regular updates for all staff involved in the prescribing, preparation and administration of epidurals that incorporate the following:

  a) Patient Assessment - pain score at rest and on movement, blood pressure, pulse rate, oxygen saturation, respiratory rate, urinary output, sensory and motor blockade, nausea score, sedation score, fluid balance. Pressure area care must be included. These observations must be linked to an early warning scoring system on a single observation chart.

  b) Prescribing – epidurals must be prescribed by an authorised prescriber who has undergone competency based training for the prescribing of epidural medication. The following information must be recorded on the initial epidural prescription chart; the level of insertion of epidural catheter, length of catheter in epidural space, distance from skin to epidural space, initial dose of local anaesthetic +/- opioid.

  c) Preparation and administration – epidurals should only be maintained in areas where epidural analgesia is regularly employed and where sufficient staff have received competency based training in epidural analgesia. Patent IV access must be maintained for the duration of the epidural. Oxygen must be available at the patient's bedside. Training must include the use of ready to administer infusions, second independent check by a practitioner who has also been trained in the administration of epidurals, priming of device according to manufacturers' instructions, use of in-line filters, labelling of the epidural line and administration of top up/bolus doses, epidural catheter discontinuation, decontamination and disposal.

d) Indications for supplementary local anaesthesia include - missed segment, sensory blockade below level of wound, unilateral blockade, re-establishing epidural, and pain score unacceptable. Local anaesthetic +/- opioid can be administered either via the epidural device or using an ampoule of a more concentrated solution. A test dose must be administered in the latter case.

e) Side effects – Recognition and management of adverse effects including: respiratory depression, excessive sedation, hypotension, bradycardia, high sensory and dense motor blockade, urinary retention, nausea and vomiting. Staff must be aware of the signs of less common but potentially serious complications such as total spinal, epidural abscess/haematoma, local anaesthetic toxicity.

- A regional template for the management of epidural analgesia will be developed this will include; prescription, administration, monitoring, management of complications.

Audit

Trusts should ensure that an audit of epidural practice is completed at least annually. This should ensure that practice adheres to NPSA recommendations, Royal College of Anaesthetists Good Practice Statement 2004 (www.rcoa.ac.uk) and local procedures. Audit results should be reviewed alongside local patient safety incident data concerning the use of epidural medicines.

Appendix 1

Group members

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David Hill, Anaesthetist – obstetrics, SET
Ron Cooper, Anaesthetist – chronic pain, NT
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Julia Tolan, Pharmaceutical procurement, BT
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Remit

- Represent the views of your profession / speciality at regional level to allow the work to progress in a consistent manner.
- Feedback the work of the group to your local implementation group and professional/speciality groups.
- Review the NPSA Safety Alert 21 and agree a regional approach to action points and implementation.

Recommendations to be agreed by the group

- Rationalise the range of epidurals products available including maximising the use of ready-to-administer epidurals.
- Agree regional standard for epidural labels.
- Agree audit tool for the use of epidurals injections and infusions for annual audit.
- Agree regional standards for the supply and storage of epidurals.
- Agree regional procedures for labelling epidurals administration sets and epidural catheters.
- Agree regional standards for epidural infusion pumps and syringe drivers.
- Develop a template for the development of training programmes and competency based assessments for all staff involved in the prescribing, preparation, administration, and monitoring of epidural infusions and injections.