NatPSA/2025/007/DHSC: Supply of Licensed and Unlicensed Epidural Infusion Bags

Additional Clinical guidance

A safety critical and complex National Patient Safety Alert was published on 2 December in response to shortages of commercially prepared epidural infusions.

During this period of supply disruption, hospitals may be supplied with substitute products, different to their usual epidural infusion bags.

As outlined in the National Patient Safety Alert, all Trusts are required to assemble a multiprofessional working group under the leadership of an appropriate senior anaesthetist, in order to undertake a set of required actions and oversee the safety of patients in relation to this supply disruption.

This guidance aims to support Trust working groups in developing and implementing their safety actions.

General Advice

The working group should prioritise available stock for specific patient groups/ procedures and should consider the following points when making their decisions:

- Overall, there is little clinical difference between bupivacaine and levobupivacaine for epidural infusions; however there are specific considerations for children and young people, and for women in labour (see below)
- Bags may be supplied with a concentration of 0.1% or 0.125% local anaesthetic. Whilst switching from the higher to lower concentration will not impact patient safety, there are safety implications in using the higher concentration (0.125%) in clinical areas which are accustomed to using the lower concentration (0.1%).
    - In obstetrics evidence that higher concentrations of local anaesthetics are associated with more interventions, which has led to the almost universal use of 0.1% bupivacaine and Levobupivacaine for labour analgesia in the UK.
    - In paediatrics particular caution is needed around the maximum safe dose when switching between 0.1% and 0.125% especially within lower weight younger children.
- Bags may be supplied as local anaesthetic only or local anaesthetic plus fentanyl. Where fentanyl needs to be added to local anaesthetic bags for epidural infusions, this should be undertaken in pharmacies' aseptic facilities. The preparation of infusions in clinical areas poses significant safety risks and should be a last resort only.
- Bags may be supplied in 250ml or 500ml sizes. Standard Operating Procedures (SOPs) should take into account the possibility of a different bag size to normal being supplied to clinical areas.

Obstetric-specific considerations

- Use of 0.125% rather than 0.1% bupivacaine for labour analgesia may be associated with an increase in obstetric interventions and increased motor block – for these

reasons, Trusts may choose to prioritise women in labour for 0.1% bupivacaine if available.

Paediatric-specific considerations

- Epidural pump protocols (infusion and bolus) should be reviewed to ensure that the maximum safe dose is not exceeded when switching between 0.1% and 0.125% concentrations, especially for lower weight children.

The challenges associated with the supply disruption should be monitored using normal clinical governance procedures, including the Trust risk register where appropriate and recording incidents and near misses.

Date of Issue: 16th December 2025

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