



National Patient Safety Agency

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Introduction of safer spinal and epidural devices will reduce risk of wrong route errors

The National Patient Safety Agency (NPSA) has today announced an initiative that will see the NHS and healthcare industries develop safety design solutions which will improve patient safety.

The NPSA's latest Patient Safety Alert advises all NHS organisations across England and Wales to introduce purchasing for safety initiatives to eliminate the use of luer universal connectors and intravenous infusion spikes in spinal (intrathecal), epidural and regional devices. This should further minimise the risk of wrong route errors.

NHS organisations are being asked to ensure that all spinal (intrathecal) bolus doses and lumbar puncture samples are only performed using syringes, needles and other devices with connectors that will not also connect with intravenous luer connectors. The deadline for compliance to this Patient Safety Alert is April 2011.

The Patient Safety Alert also stresses the need for all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses to be performed with devices with safer connectors that will not connect with intravenous luer connectors and intravenous infusion spikes by April 2013.

Welcoming today's announcement, Chief Medical Officer for Wales, Dr Tony Jewell said: "This is another example of how the NHS is continually evaluating its work and introducing measures to further reduce risks and improve care for patients.

"This complements the work of the 1,000 Lives Campaign, which aims to improve patient safety in Wales."

Acting Chief Pharmaceutical Adviser for Wales, Jeremy Savage, said: "Improving the safety of spinal and intracranial administration of medicines is of paramount importance. Achieving the elimination of a cause of avoidable harm to patients by this mechanism will be a huge step forward in delivering safer patient care. The design of devices with patient safety as the prime objective is a very welcome development for the NHS."

The NPSA's Medical Director, Dr Kevin Cleary, said: "Luer connectors are used thousands of times each day by NHS clinicians without any complications or problems. This Patient Safety Alert will further reduce any chance of wrong route errors which can lead to patient harm. This will make safe care even safer.

"The NHS will become the first healthcare system in the world to implement medical devices with safer designs for spinal, epidural and regional anaesthesia use."

NPSA's Head of Safe Medication Practice, Professor David Cousins, said: "Devices with safer connectors are not currently available. By issuing this alert the NHS is stating clearly to medical device manufacturers and the pharmaceutical industry that it will only buy products that facilitate safe practice in the future.

"The timescales within the alert give NHS organisations adequate time to ensure they have systems in place to introduce the devices with safer connectors by the specified deadline."

In the past, there have been fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route and epidural medicines have been administered by the intravenous (vein) route.

The last reported fatal wrong route incident involving epidural medicine was in February 2007. There have been no further reports of intravenous vincristine being administered by the spinal route in the UK, but additional deaths have occurred in other countries.

In addition, there have been 18 low or no harm incidents reported to the NPSA between 1 January 2008 and 31 July 2009, where misconnection errors have occurred. This has meant drugs intended for one route of administration (for example, spinal or epidural) have been administered via an inappropriate route.

Professor Ravi Mahajan, Chairman of the Royal College of Anaesthetists' Safe Anaesthesia Liaison Group, said: "This is an excellent example of the NPSA and professional bodies working together to improve the existing systems to minimise risks from wrong route errors in patients requiring drug administration for spinal, epidural or regional anaesthesia/analgesia. The implementation of this Alert, no doubt, will significantly improve patient safety in clinical practice."

Since 2001, the NPSA has been working with healthcare organisations and manufacturers to ensure that safety changes are made in the design of medical devices used to administer medicines for spinal, epidural and regional anaesthesia procedures.

Professor Cousins added: “Manufacturers are fully aware of the NHS’ new purchasing for safety requirements. They have indicated that they are striving to respond to these requirements within the identified timescales.”

The NPSA has previously issued guidance to minimise the risks of wrong route epidural incidents, and the Department of Health has issued guidance on intrathecal chemotherapy.

The introduction of devices with safer connectors does not replace this guidance, but is intended to further reduce risk of wrong route errors.

Dr Andrew Hartle, Chairman of the Association of Anaesthetists’ Safety Committee, said: “Now that this Patient Safety Alert has been issued, anaesthetists should engage with local processes to make sure this is a priority for their organisation. Clinical engagement is vital if we are to avoid being forced to accept products that either do not work or are less easy to use than the current equipment.”

Harrie Cooke is Secretary at Barema, a trade association that promotes co-operation between registered companies engaged in the manufacture, distribution and servicing of anaesthetic and respiratory equipment.

He said: “Anaesthetic and respiratory equipment has always had an enviable reputation for innovation, quality, safety and reliability. These factors have undoubtedly contributed to the outstanding success the industry has achieved in both domestic and overseas markets.

“One of our key aims is to continually strive to improve patient safety, by working closely with clinicians, Department of Health, agencies and standards bodies. Clearly with this latest Patient Safety Alert from the NPSA, manufacturers have a vital part to play in making the safe even safer.”

For more information, or to download the Alert, please visit www.nrls.npsa.nhs.uk

-ENDS-

Notes to Editors:

Luer connectors were developed early last century to connect hypodermic and intravenous devices. Over the years they have been used in other devices including those for spinal, epidural and regional use. When different types of devices can be physically connected together there is a risk of wrong route errors.

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2. The **National Patient Safety Agency** (NPSA) is an Arm's Length Body of the Department of Health. It encompasses three divisions; the National Research Ethics Service, the National Reporting and Learning Service and the National Clinical Assessment Service. Each has its own sphere of expertise to improve patient outcomes. The NPSA's vision is to lead and contribute to improved, safe patient care by informing, supporting and influencing healthcare individuals and organisations. For more information visit: www.npsa.nhs.uk.