Introduction
In our last newsletter in October 2011 we described a patient safe ty incident where a spinal needle with a non-Luer connector had been supplied and used in error, when a device with a Luer connector was intended. Treatment had to be delayed as there were no compatible non-Luer syringes available for use with the spinal needle. The needle had to be removed and a second spinal needle with a Luer connector obtained and the treatment procedure went ahead as intended.

Rapid Response Report
The NPSA issued a Rapid Response Report on Minimising Risks of Mismatching Spinal, Epidural and Regional Devices with Incompatible Connectors on 28th November 2011. All organisations in the NHS and independent sector who use spinal and intrawe re recommended to implement the following action by 31 March 2012:

RRR Recommended Actions for Healthcare providers
- Alert healthcare staff who order, receive, transport, restock and clinically use spinal, epidural and regional devices of the risk of mis-matching connectors.
- Check current stocks of spinal, epidural and regional devices to ensure these devices are compatible.
- Amend written distribution and clinical procedures to confirm the identity of the connectors used in devices. Checks should not solely rely on catalogue code numbers. The term ‘Luer’ and where neuraxial connectors are fitted, the device trademark should be used identify different connector designs. Currently Correctinject®, Hall Lock®, Neurax®, Surety®, UniVia® are trademarks being used. Only devices with the same connector descriptors are compatible. In addition other design elements such as colour, text and symbols should assist users identify the type of connector used in the device.
- Use procedure packs where feasible and appropriate to ensure that all the devices required for a specified procedure are compatible and readily available.
- Recommend clinical staff check all devices required for a procedure are fitted with the same connector design before commencing the procedure.

Recommended safer designs for device manufacturers
The Rapid Response report also indicated that The National Patient Safety Agency (NPSA) has alerted device manufacturers of this risk and will promote the need for safer design. This will include the use of colour, wording and symbols, on neuraxial devices, labelling, packaging and shipping cartons, to clearly indicate the type of connector used in these devices.

The NPSA External Reference Group For Safer Neuraxial Devices including representative from industry considered design issues in November 2011. The Group reviewed and supported the use of the words and symbols shown in Figure 1.

Device manufacturers, including those producing devices with Luer connectors, are recommended to include and give prominence to the appropriate design in Figure 1.

Figure 1
Recommended symbols and text for use in neuraxial device labelling

- **LUER**
- **Correctinject**
- **Hall Lock**
- **Neurax**
- **Surety**
- **UniVia**
Guidance from the European Medicines Agency

The European Medicines Agency is aware of three fatal cases of administration error that occurred with bortezomib (Velcade). Two cases were reported in Italy and one in France. The incidents involved the medicine accidentally being administered intrathecally instead of intravenously.

The Agency's Committee for Medicinal Products for Human Use (CHMP) has issued guidance to healthcare professionals alerting them of these incidents and risk and recommending precautionary measures to prevent further administration errors from occurring.

The NPSA has contacted the EMA and manufacturer to inform them of the Neuraxial device initiative in the UK.

EMA recommendations for healthcare professionals

Healthcare professionals are reminded that bortezomib (Velcade) should only be given intravenously and are advised to consider the following precautionary measures:

- When possible, different connectors should be used for medicines to be administered via intrathecal or intravenous route.

- When possible, intrathecal chemotherapy should be administered at a different time than any other parenteral chemotherapy (chemotherapy given by injection or drip into a vein).

- Syringes should be clearly labelled with the name of the medicine and route of administration to be used.

- Procedures should be in place for double checking the labelling of syringes before administration.

- Intravenous and intrathecal injections should be handled only by suitably trained healthcare professionals.

- Healthcare professionals involved in administration or management of cancer chemotherapy should be trained and informed of the dangers of intrathecal administration of bortezomib (Velcade) and of the recommended measures to prevent this from occurring.

What is bortezomib (Velcade)?

Velcade is an anticancer medicine that contains the active substance bortezomib. It is available as a powder that is made up into a solution for injection into a vein. Velcade is used to treat patients with multiple myeloma, a cancer of the plasma cells in the bone marrow.

The active substance in Velcade, bortezomib, is a proteasome inhibitor. It blocks the proteasome, which is a system within the cells that breaks down proteins when they are no longer needed. When the proteins in the cancer cells, such as the proteins that control the growth of the cells, are not broken down, the cells are affected and they eventually die.

Velcade has been authorised in the European Union since 26 April 2004 and is marketed in all Member States as well as Norway, Iceland and Liechtenstein by Janssen Pharmaceutical Companies.
Two New Connector Designs For Neuraxial Infusions

Method for adding additives for epidural infusions

How could medicines be added to epidural infusions with the new connector designs? What provision was made for additive ports?

Both companies developing new connector designs for neuraxial infusions indicated that no changes were planned. Users can continue to do what they do currently.

Some commercial infusion containers contain no additive ports and no additives are possible.

Other infusion containers have rubber additive ports and medicine additive can be made using Luer syringes and hypodermic needles. It would still be possible for intravenous medicines to be added to epidural infusions fitted with new neuraxial connectors using additive ports.

Further discussion is required on how additives to epidural infusions will be handled.

Please send us your views in this issue.

NonivLok connector design

In the last newsletter in October 2011 we announced Chapter has designed and developed a safer neuraxial connector infusion spike, which is protected under patent application and registered under the “NonivLok” trademark.

The NonivLok female port is incorporated into the pharmaceutical product container and uses a central ‘defence plug’ of thickened material that resists penetration from intravenous male spike connectors. The defence plug is surrounded by a thin annular septum which is designed to catastrophically fail if the attempt to connect persists with increasing force. Such a catastrophic failure leads to leakage of infusion fluid while this is undesirable, this feature prevents infusion administration and will minimise the risk of wrong route administration.

The NonivLock male connector uses dimensionally constrained teeth to connect with and penetrate the female connector. The leading perpendicular edge and teeth prevent connection with intravenous female infusion ports. The NonivLok is currently configured in three presentations:

- 20mm DIN neck aperture containers
- 32mm Din neck aperture containers
- Semi-rigid polypropylene bags

NonivLok has commissioned independent testing program and independent evaluations in clinical settings.

The Surety Spike

The Surety Spike has been developed by Intervene and has been designed to fit into existing infusion container ports.

The device has a retracted spike at one end and a Surety neuraxial connector at the other. The Surety Spike would be permanently attached to the infusion container port. When a neuraxial infusion is required an neuraxial administration set is connected to the infusion container using a Surety neuraxial connector. By doing this the retracted spike would be activated within the infusion port and a fluid pathway would be established with the administration set.

Surety Spike connectors will be available to other manufacturers in early 2012.
New Product Assessment Checklist For Neuraxial Devices

Technical and usability information to support purchasers select new devices

The NPSA External Reference Group on Neuraxial Devices has advised that NHS clinicians and other healthcare staff wish to be well informed about new devices with safer connectors coming onto the UK market. The group has recommended that suppliers should provide the NHS with independent technical and usability test results of new devices, that will assist the procurement process. Test results should be from independent laboratories which are accredited to ISO 17025 and have experience testing medical devices or microbiology.

Recommended devices and sizes of devices

The NPSA has recommended a list of devices required for organisations to meet Part A requirements for spinal (intrathecal) and lumbar puncture use.

Independent test information is required on the following:

Technical laboratory testing results on:

- security of connection;
- ease and force of separation;
- leakage tests;
- ease of thread engagement;
- cross connectivity with Luer and other small bore connectors;
- microbiological integrity testing of prefilled syringes.

Clinical simulation test results using an anatomically realistic spinal trainer manikin should include four simulated clinical settings:

- spinal anaesthesia;
- epidural analgesia and anaesthesia;
- intrathecal chemotherapy;
- lumbar puncture.

Simulation results from the clinical settings above should include:

- clinical acceptability;
- user satisfaction;
- cross connectivity with Luer and other small bore connectors.

Details of recommended methods for independent technical and usability testing are available from the

The following range of devices with NPSA compliant connectors is recommended for NPSA Part A guidance

- Spinal needles - Quincke and pencil point
e.g. Sprotte, Whitacre;
- Lengths: 40-150mm;
- Gauges: 18, 19, 20, 22, 24, 25, 26, 27;
- Introducer needles
- Syringes - both slip and lock connectors;
  sizes: 1, 3, 5, 10 and 20ml.
- Filters – 0.2 micron and 5micron;
- Filter needles;
- Drawing up needle (sharp) 19G;
- Spinal manometer.
- Syringe cap;
- Fluid dispensing connector.
- Three way tap.
- Winged needle and tube (butterfly device) for use with Omayer reservoirs

Independent evaluation results

Univia

Surety
Intervene. Sterility tests of the internal contents of twelve Surety syringes with caps. 2011
Cass Industries. Syringe test for SURETY 1-10mL syringes to IEC/CD 80369-1 and IEC/CD 80369-6. 2010

Neurax
Dr Paul Sharpe, Consultant Anaesthetist is co-ordinating a structured evaluation of the new neuraxial devices in University Hospitals of Leicester NHS Trust.

Spinal needle devices with six non-Luer connector designs are being evaluated. Vygon and Braun were unable to supply samples and are not part of the evaluation.

The clinical evaluation process being used was based on the OAA evaluation form that had been circulated.

There are four stages to the evaluation,

1) Bench test of flow characteristics 
2) Pilot assessment by one clinician to ensure no gross technical/use problems
3) Clinical assessment by lead anaesthetists within the Trust
4) Top three connector designs from previous stages to be evaluated by medicine, oncology and paediatric clinicians

The initial anaesthetic evaluation was expected to be completed by the end of March 2012. The evaluation process is expected to be completed in June or July 2012

Dr Mike Kinsella, Consultant Anaesthetist is co-ordinating a structured evaluation of the new neuraxial devices in University Hospitals Bristol.

Spinal devices from Smiths, Sarstedt, Blue Box and Pajunk were being evaluated.

There was a clinical requirement for lock connectors and suppliers unable to provide these types of connector were not included in the evaluation.

The clinical evaluation process being used was based on the OAA evaluation form that had been circulated. Evaluations were taking twice as long as was planned.

The evaluation process is expected to be completed by the end of March.
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Details of devices currently available are available as a Newsletter appendix in the Patient Safety First Website at:
Frequently asked questions

4.1 Are winged needle infusion (Butterfly) devices with non-luer connectors necessary to achieve compliance with the NPSA alert?

Our previous guidance on this (included in the October 2011 newsletter) has been revised and this type of device has been added to the list of devices requiring a non-Luer connector for Part A Guidance.

4.2 Are 1ml, 10ml and 20ml syringes required for Part A recommendations?

1ml syringes are used for Part A procedures. Some clinicians use them to inject patients directly in paediatric anaesthesia and also in oncology.

Others are using them as part of medicine mixing exercise in spinal anaesthesia, e.g. when adding diamorphine to bupivacaine solutions.

1ml syringe with neuraxial connectors will be essential for full Part A compliance in most NHS organisations.

Some intrathecal doses of chemotherapy for paediatric patients require final volumes of between 6 – 10ml and these doses require a 10ml syringe with a neuraxial connector for use in dose preparation and administration to comply with Part A recommendations.

A 20ml syringe is used for concentrated morphine and bupivacaine to refill implantable neuraxial pumps. A 20ml syringe also be required for epidural blood patch therapy to meet Part B recommendations.

FAQ’s that appeared in previous newsletters

Issue 3 – October 2011

3.1 Spinal catheters
3.2 Winged needle infusion devices
3.3 Spinal needles to aspirate knee joints.
3.4 Local anaesthetic wound infusion devices
3.5 Short spinal needles for children
3.6 Tamper evident syringe caps

Issue 2 – February 2011

2.1 External-ventricular drains
2.2 Are Ommaya reservoirs
2.3 Neuro-endoscopes
2.4 Three-way taps
2.5 Sub-tenon anaesthesia
2.6 Epidural blood patch technique
2.7 Bier’s Block’s
2.8 Definitions for regional and local anaesthesia
2.9 All possible cross connections?
2.10 Misconnection with needle free connectors
2.11 Devices to administer local anaesthetics into the skin prior to neuraxial procedures

Issue 1 – August 2010

1.1 who is responsible for managing the introduction of safer devices in NHS organisation?
1.2 How should the new devices be introduced into clinical practice?
1.3 What degree of training is necessary? 1.4 Can’t this work be undertaken nationally or regionally?
1.5 What is the status of combined and epidural kits (CSE)?
1.6 What is the status of Loss of Resistance Syringes (LOR) are they covered by Part A or Part B guidance?
1.7 What if non-luer 10ml and 20ml syringes are not available by April 2011?
1.8 I ISO neuraxial standard development

Q: Where can I get more information on the implementation of new neuraxial devices in the future?

A: The NPSA plans to issue more editions of the Neuraxial Update in the future. In addition FAQs and information concerning new devices will be updated more frequently. The information will be available on the NPSA website at: http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=94529


This site also has a neuraxial device forum to discuss and share experience of implementing devices with safer connectors.

Welsh Neuraxial Reference Group
http://smtl.co.uk/

Neuraxial testing programme - Wales
http://smtl.co.uk/nhs-services/58/157-neuraxial-non-luer.html

Obstetric Anaesthetists Association
http://www.oaa-anaes.ac.uk/content.asp?ContentID=367

Association of Anaesthetists Newsletter