Design for patient safety

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 route.

There is also the potential for medicines intended for regional anaesthesia to be administered by the intravenous route, with fatal outcomes.

These wrong route errors will always be possible as long as medical devices with standard (Luer) connectors are used.

The introduction and use of medical devices which do not physically connect with intravenous equipment will further reduce the risk of wrong route errors.

National Patient Safety Agency

New timelines for implementation

A Patient Safety Alert Update was issued on 31 January 2011 by the NPSA. The Alert Update announced a change of implementation completion date for Part A guidance from 1 April 2011 to 1 April 2012.

The implementation completion date is being changed to provide healthcare organisations with additional time to review and evaluate the range of new devices and test information available, introduce these new devices into practice, and take action required to minimise any potential practice risks arising from the use of these new devices by healthcare practitioners.

By 1 April 2012 the following actions will have been completed:

- all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that will not connect with intravenous Luer connectors.

Safer devices should be introduced into practice as soon as possible and without undue delay during 2011 in order to comply with the implementation deadline of 1 April 2012.

Part B guidance concerning epidural therapy, spinal infusions and regional anaesthesia and support information remains unchanged. No further changes to implementation target dates for Part A and Part B guidance are anticipated.

In this issue

New information about devices

Flexicare have launched a range of Hall Lock spinal needles and syringes. The following products are available:

- pencil point spinal needles 22g – 27g;
- spinal syringes 1ml, 3ml, 5ml and 10ml.

Becton Dickinson are planning to supply the following devices:

April 2011
- a wide range of spinal needles with Whitacre or Quincke tip types, with various gauge sizes from 18 to 27G, and lengths of 38 to 127mm;
- Non-luer introducer needles for Whitacre 25G and Whitacre 27G
- Syringes and blunt filter needles.

June/July 2011
- syringe caps for chemotherapy;
- compatible lumbar puncture devices (manometer, 3-way-tap) and kits.

B Braun Medical have announced:
- a full range of SafeConnect Spinal needles which are compatible with the Surety accessory portfolio including syringes, caps and filling devices;
- the spinal needle portfolio will include a wide range of sizes: 18G to 27G, 40mm to 120mm;
- custom procedure packs will also be provided with B Braun spinal needles and Surety syringes and accessories.

CME McKinley are planning to supply the following devices:

First half 2011
- BodyGuard epidural infusion sets featuring the InterVenSurety connector enabling the widely used CME BodyGuard 545 Epidural infusion system to be compatible with all downstream devices fitted with Surety connectors.

Supply Chain

Supplier demonstration days

In support of the NPSA Patient Safety Alert on safer spinal (intrathecal) epidural and regional devices, and in conjunction with the NPSA and contracted NHS suppliers of relevant devices, NHS Supply Chain are in the early stages of arranging intrathecal demonstration days for the NHS.

Please contact NHS Supply Chain to register your interest at sharps@supplychain.nhs.uk
The cost of new devices

The cost of devices with safer connectors may be more than the cost of existing devices with the universal Luer connector.

As new devices are placed on the market, the NPSA, working with NHS Supply Chain and Welsh Health Supplies, will collate the cost of the new devices and communicate this information to both healthcare commissioners and service providers to enable cost-effective purchasing and financial planning.

Labelling and colour of new devices with safer connectors

Until formally recognised standards are developed, healthcare organisations should ensure that all specified devices and medicines used with these devices are clearly labelled to indicate their use, e.g. for spinal (intrathecal), epidural, regional use only.

The term ‘neuraxial’ is not clearly understood by all healthcare staff and is not recommended to be used on device labels or in packs.

The use of the colour yellow is widely used by healthcare manufacturers and practitioners on labels and devices to help reinforce that these products are for a specified route and not for intravenous use.

Supplier contact details

**B-Link (UK) Limited**
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Hospital Care, Thorncliffe Park, Sheffield. S35 2PW
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Contact Nav Gill
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Web: www.bbraun.com

**Becton Dickinson Medical**
The Danby Building, Edmund Halley Road, Oxford Science Park, Oxford. OX4 4DQ
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E-mail: gemma_bianchini@europe.bd.com
Website: www.bd.com

**Bluebox Medical Limited**
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**Flexicare**
Cynon Valley Business Park, Mountain Ash.
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Website: www.halllock.com

**InterVene Limited**
Waterloo Court, Markham Lane, Chesterfield. S44 5HN
Telephone: 07976 425653
Email: mroot@ivltd.co.uk
Web: www.suretydevices.com

**CME McKinley UK Limited**
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**Smith Medical International Limited**
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Website: www.vygon.com
The importance of microbiological integrity testing of prefilled neuraxial syringes

All intrathecal chemotherapy has to be prepared in chemotherapy safety cabinets in hospital pharmacy departments. Neuraxial syringes with safer connectors filled with chemotherapy will need to be capped and then transported to clinical areas for intrathecal doses to be administered.

It is essential that all manufacturers of neuraxial syringes provide a dedicated syringe cap for this purpose and test results of microbiological integrity testing of the capped syringes.

The NHS Pharmaceutical Quality Assurance Committee has produced a protocol for this test.

Device manufacturers should arrange for this testing to be undertaken and the results of these tests to be provided to NHS purchasers.

Details of tests

A batch or at least 20 syringes filled with sterile Tryptone Soya Broth (TSB) are sealed with the appropriate cap. These broth filled syringes are pre-incubated at 20-25°C for seven days, then 30-35°C for seven days to ensure that the aseptic fill has been carried out correctly and the contents are sterile. Any syringes showing turbidity or microbial growth are discarded.

Whole immersion test.

Inoculate a container(s) housing the syringes immersed in broth with 1 ml of the 18-24 hour culture of *Brevundimonas diminuta*. Incubate the containers for fourteen days at 30-35°C. Following incubation remove syringes from the broth culture and examine each syringe for turbidity/growth showing *Brevundimonas diminuta* access into the syringe. The integrity of the syringe/hub system is confirmed providing that the broth in all syringes remains free from microbial growth.

Partial Immersion test

This is a specific test to challenge areas where micro-organisms may gain access to the contents of the syringe such as at the plunger barrel interface, or at the hub Luer fitting. A suitably sized holder is used to ensure that the syringe(s) under test are held upright.

The upright syringes, with the plunger uppermost, are placed in a holder. The barrel of the syringe is filled above the plunger with the seeded broth culture of *Brevundimonas diminuta*; or the hub end of the syringe is placed in a bottle of TSB broth sufficient to cover the hub and inoculate with *Brevundimonas diminuta*. Incubate the containers for 14 days at 30-35°C.

Following incubation remove syringes and check for turbidity indicating the penetration of *Brevundimonas diminuta* into the syringe contents. The integrity of the syringes/hub system is confirmed providing that the broth in all syringes remains free from microbial growth.

A NHS group has been established to work with suppliers to produce microbial test information concerning their products. More information is available from the NPSA by emailing medicationteam@npsa.nhs.uk.
Frequently asked questions

External-ventricular drains are silastic tubes that enter the ventricles of the brain to treat hydrocephalus and to give intrathecal drugs (usually antibiotics). Are these devices covered in the NPSA Alert?

In the NPSA Patient Safety Alert issued in November 2009 the following definition of ‘spinal or intrathecal’ was included:

Administer ‘spinal’ medications (e.g. intrathecal chemotherapy, anaesthetics, radiological contrast agents, antibiotics and analgesics) via the intrathecal space including the ventricles of the brain. The terms ‘spinal’, ‘subarachnoid’ and ‘intrathecal’ are equivalent and describe the fluid filled space surrounding the spinal cord and brain.

Part A guidance is for spinal (intrathecal) bolus administration and sample collection, involving the use of syringes and needles only. Part B guidance is for spinal (intrathecal) procedures involving tubing. External-ventricular drains involve the use of tubing and are therefore out of scope of the NPSA Alert.

Are Ommaya reservoirs covered by NPSA guidance?

An Ommaya reservoir is an intraventricular catheter system that can be used for the aspiration of cerebrospinal fluid or for the delivery of medicines into the cerebral spinal fluid. It consists of a catheter in one lateral ventricle attached to a reservoir implanted under the scalp. Medicines are administered through the scalp and into the reservoir using a syringe and needle and no tubing is used. This method of administration is covered by NPSA Part A guidance.

Neuro-endoscopes have luer connectors for connection directly to giving sets so saline can be irrigated into the ventricles during the operation. Guidance please?

The devices used with neuroendoscopes to connect giving sets involve tubing and are therefore covered by Part B guidance.

The NPSA Alert states ‘eliminate the use of three-way taps and adaptors with Luer connectors, which enable connection of specified devices to intravenous devices.’ Please clarify exactly what is meant by this guidance?

Safeguards to prevent wrong route errors included in the design of the safer connectors can be bypassed by using adapters and 3-way taps with Luer connectors that will enable connection to intravenous devices.

No loose adapters should be used with neuraxial devices with safer connectors in clinical areas. Adapters may be bonded to neuraxial devices during the manufacturing process and supplied to the NHS as part of neuraxial devices.

Only 3-way taps with safer connectors included in neuraxial procedure packs should be used.

On no account should any type of intravenous 3-way tap device be used with the safer neuraxial devices.

Is sub-tenon anaesthesia covered by the alert, and if so which part of the alert covers it?

The technique of sub-tenon anaesthesia using a blunt needle has become the procedure of choice for ophthalmic anaesthesia. In this procedure 3 - 5ml of local anaesthetic is injected.

In the NPSA Alert definitions were provided for regional and local anaesthesia. These definitions are reproduced as a FAQ in this newsletter.

Devices for local anaesthesia are not covered by the Alert.

According to these definitions Sun-tenon anaesthesia is classed as a local anaesthetic procedure and is therefore not covered by the NPSA guidance.

How should the epidural blood patch technique be undertaken with safer neuraxial devices in the future?

The epidural blood patch technique is where a small amount of the patients own blood is injected into the epidural space near the site of a hole in the dura mater. The resulting blood clot ‘patches’ the dural leak.

This technique is covered by guidance in Part B of the NPSA Alert with a target implementation date of 1st April 2013.

The blood patch technique will require blood to be taken, under strict aseptic conditions, from the patients’ vein using a 20ml syringe and hypodermic needle with safer connectors. The blood is then injected into the epidural space via a Tuohy epidural needle incorporating the safer connector.

This hypodermic needle should ideally be presented in a specific pack for blood patch use only. The pack would contain all standard equipment needed for a blood patch. Where this is not possible the needle should be clearly labelled for blood collection only and stored away from standard luer hypodermic needles to minimise the risk of mis-selection and mis-use.

Are Bier’s Block’s covered by the Alert?

Bier’s block is an intravenous regional anaesthesia technique in which an extremity (generally an arm) has a tourniquet applied and local anaesthetic solution is administered prior to a clinical procedure. Bier’s block requires intravenous administration and is therefore out of scope of the NPSA Alert.

Medical devices with Luer connectors intended for intravenous use should be used.

What are the definitions for regional and local anaesthesia used by the NPSA?

Regional administration

Regional infusions (e.g. anaesthetics) affecting a large part of the body, such as a limb, and includes plexus blocks such as brachial plexus blocks and single nerve blocks. For the purpose of this guidance it will also include the continuous infusion of wounds with local anaesthetic agents.

Local administration

Local anaesthesia is anaesthesia of a small part of the body, such as a tooth or a small area of skin, and devices for this form of anaesthesia are not included in this guidance.
Frequently asked questions continued

The NPSA Alert states that neuraxial devices with safer connectors should not connect with intravenous Luers. Does this include all possible cross connections?

The main aim of the NPSA Alert was to reduce the risks of accidental wrong route errors by mis-connection such as intravenous medicines being administered by neuraxial routes and neuraxial medicines being administered by the intravenous route.

The guidance does not eliminate all risks. For instance, it does not prevent the deliberate drawing up of an intravenous medicine into a non-Luer syringe intended for spinal administration.

It may not be possible to eliminate misconnections in all directions. During equipment testing it has sometimes been found that non-Luer syringes may connect to Luer or oral syringes, because some of the new designs use a female-male sequence in their connectors rather than the conventional male-female. These misconnections pose less risk to patients as they will not occur accidentally but only by deliberate misuse.

The ideal neuraxial connector design would not connect with other connectors in either direction. However, the engineering challenge to achieve this is high.

The NPSA Alert requires the use of safer connector designs to prevent the specified wrong route errors with intravenous devices. During the purchasing for safety selection process the essential outcome is that equipment is identified that does not allow accidental cross-connection of neuraxial, intravenous and enteral equipment when used in clinical configurations.

Should safer connectors, used in neuraxial devices, connect with needle free connectors and bionnectors used in intravenous devices?

No.

Should syringes and needles used to administer local anaesthetics into the skin have safer connectors?

Only devices used to take samples or administer medicines by the spinal, epidural or regional routes should have safer connectors. Those intended for intravenous and hypodermic use, including those to administer local anaesthetics into the skin should use devices with Luer connectors.

There is some confusion over the product range required to implement NPSA Alert Part A guidance. Is a recommended product range available for information?

The following range of devices with NPSA compliant connectors is recommended:

- 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 – 5micron;
- Filter needles;
- Drawing up needle (sharp) 19G;
- Spinal manometer.

- Syringe cap;
- Fluid dispensing connector.

- Three way tap.

Having reviewed the range of devices listed above, is there an essential medical device required for a spinal (intrathecal) procedure covered by NPSA Part A that is not listed? Please contact the NPSA with details of the missing device and indicate the clinical procedure where the device is required. Please send details to: medicationteam@npsa.nhs.uk

References and other information


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/?Entr yId45=65259 and on the Patient Safety First website at: http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/interventions/relatedprogrammes/medicationsafety/safer-neuraxial-devices

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