Implementing Medical Devices With Safer Connectors

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The ‘Universal’ Connector
Action for the NHS

1 Design and supply of syringes used to administer oral liquid medicines
   • Only use well-labelled oral and enteral syringes that cannot be connected to intravenous catheters or ports to measure and administer oral liquid medicines.
   • Do not use intravenous syringes to measure and administer oral liquid medicines.
   • Make sure stocks of oral and enteral syringes are available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe.
   • If patients or carers need to self-administer oral liquid medicines with a syringe then supply them with oral or enteral syringes.

2 Design of enteral feeding systems
   • Enteral feeding systems should not contain ports that can be connected to intravenous syringes or that have end connectors that can be connected to intravenous or other parenteral lines.
Safer Enteral Devices
Device connectors & infusion spikes

THE AGONY OF HINDSIGHT

Wayne Jowett - 2 February 2001

Vincristine inadvertently administered intrathecally

Mayra Cabrera - 11 May 2004

Bupivacaine inadvertently administered intravenously

Joseph Gibbs - February 2007

Bupivacaine and fentanyl inadvertently administered intravenously

“We just hope something gets done now within the industry. It’s so fundamental.”
The answer is surprisingly mundane. It is this: we are human, and humans err. Despite outrage, despite grief, despite experience, despite our best efforts, despite our deepest wishes, we are born fallible and will remain so.

The remedy is changing the system of work and better design.
Royal College Epidural Audit

- Technical solutions, such as non-interchangeable connections, should be pursued with vigour, but must encompass the whole system from fluid reservoir to patient.

- They should only be introduced after careful assessment that they themselves do not introduce problems as a result of ‘unintended consequences’.
Paragraph 181

We are alarmed at the lengthy delay in implementing Professor Toft’s 2001 recommendation regarding the development of spinal needles that cannot be connected to a Luer syringe. It is totally unacceptable that an identified and simple technical solution to a catastrophic problem should take so long to be put into practical use. The Chief Executive of the NHS must explain why this delay has taken place and ensure that such delays never occur again. It is unacceptable that the NHS does not have a mechanism to ensure that changes such as this, which impact seriously on patient safety, occur in a timely fashion.
2000
European Standards Agency - CEN

- DS DS/CEN/CR 13825
- Luer connectors - a report to CEN Chef from the CEN forum task group ”Luer Fitting”.

- Luer connectors should be restricted to intravenous and hypodermic devices.

ISO TC 210

Small-bore connectors for liquids and gases in healthcare applications — Part 1: General Requirements
A two step process is required

Safer devices

Standardised single design
Equipment types

**Spinal**
- Spinal syringes
- Drawing-up needles
- Drawing-up syringes
- Spinal filters
- Spinal manometers
- Spinal catheters
- Spinal administration sets
- Infusion bags/bottles

**Epidural**
- Spinal/epidural needles
- Epidural syringes
- Drawing-up needles
- Bacterial filter
- Epidural catheters
- Epidural administration sets
- Infusion bags/bottles
Equipment types

Regional
- Regional syringes
- Drawing-up needles
- Regional catheters
- Wound perfusion catheters
- Regional administration sets
- Infusion bags/bottles
Safer spinal (intrathecal), epidural and regional devices – Part B

From 1 April 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses should be performed with devices with connectors that will not also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2013 implementation date. These devices with safer connectors are not currently available.

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a ‘Purchasing for Safety’ initiative to ensure that:

- All epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes.

Connector designs

Male to Female

Neurax – B-link
BD
Smiths
Flexicare

Female to Males

Surety
Univia

Current luer | Univar
---|---
Univar male to Univar female | Univar male to luer female

No connection

Univia

Safety spinal needle | Conventional spinal needle
CorrectInject® Safety System – Spinal Solution

CorrectInject® Filter Needle
CorrectInject® Syringe (3ml, 5ml, & 10ml)
CorrectInject® White Transport Cap
CorrectInject® Spinal Needle (22-27G PP / 90mm & 115mm)

REGANESTH® Spinal Needles Pencil-Point and Quincke
Safely Spinal Devices with Non-Luer S. Safety-Connectors

Epidural Anaesthesia
Safely Epidural Devices with Non-Luer S. Safety-Connectors

NPSA Compliant Products for Spinal Anaesthesia
- Prevents needle punctures and increases user safety
- Do not connect with intravenous equipment
- Spinal needles with non-Luer and Quincke needle
- REGANESTH® spinal needles pencil point with non-Luer and non-reflected plastic connector
- Quick detection of the biopsy needle due to the transparent needle hub

NPSA Compliant Products for Epidural Anaesthesia
- Prevents needle punctures and increases user safety
- Do not connect with intravenous equipment
- Spinal needles with Tuohy bowers and different lengths
- For long term anaesthesia and analgesia
Surety connectors

designed to prevent misconnections
- Haptic perception
- Visual shape recognition
- Colour recognition
Surety – Connector consortium
Polymedic
BBraun
Sarstedt
Pajunk
Vygon
Aspen Medical
Rocket Medical

New market entrants
Flexicare
Neurax B-link
Smiths

5 connector designs in response to NPSA Alert

Surety – Connector consortium
Polymedic
BBraun
Sarstedt
Pajunk
Vygon
Aspen Medical
Rocket Medical

New market entrants
Flexicare
Neurax B-link
Smiths

5 connector designs in response to NPSA Alert
Process to place new medical devices on the UK market

EU Medical Devices Directive
CE Mark

The amount of clinical testing is NOT = to that required for medicines

For new critical devices – like neuraxial devices – more clinical testing information is required by purchasers

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.
Technical and usability testing information

Technical laboratory testing results should include:
- measurements of key dimensions, for consistency of manufacture;
- 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 anaesthesia 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.

The first patient safety incident with a spinal needle with a safer connector
Rapid Response Report
NPSA/2011/RRRX
From reporting to learning

DRAFT
Minimising Risks of Mismatching Spinal, Epidural and Regional Devices With Incompatible Connectors

Issue
Spinal, epidural and regional devices, with safer connectors that will not connect with intravenous equipment are being placed on the market by industry in response to the NPSA Patient Safety Alert issued in 2005.\(^1\) Although the use of these devices will minimise the risks of wrong route errors, it is essential that effective controls are in place to minimise the risk of mis-selection and supply of devices with incompatible connectors that could cause delay in clinical procedures and harm patients. The NPSA has recently received details of a patient safety incident, where a spinal needle with the wrong connector was supplied and used in error.
1. Alert healthcare staff who order, receive, transport, restock and clinically use spinal, epidural and regional devices of the risk of mis-matching connectors.
2. Check current stocks of spinal, epidural and regional devices to ensure these devices are compatible.
3. Amend written distribution and clinical procedures and establish training programmes for staff to confirm the identity of the connectors used in devices. Checks should not solely rely on catalogue code numbers. The term ‘Luer’ and where safer connectors are fitted, the device trademark should be used identify different connector designs. Currently Correctinject, Hall Lock, Neurax, Surety, Univar 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.
4. Use procedure packs where feasible and appropriate to ensure that all the devices required for a specified procedure are compatible and readily available.
5. Apply additional labels, to clearly identify the connector design, to devices where the manufacturers labelling, packaging and shipping carton provides insufficient differentiation.
6. Require clinical staff to check that all devices for a procedure are fitted with the same connector design before commencing the procedure.

Possible Non-Luer symbols
Version 0.1 - 24/10/2011

Correctinject
Hall Lock
Neurax
Surety
Univar
New non-IV infusion spike design

‘NonivLok’

Chapter

Target implementation dates for the NHS

• Part A – Spinal bolus / lumbar puncture
  • 1st April 2012

• Part B – Epidural, Spinal Infusions, Regional Anaesthesia
  • 1st April 2013

• Ongoing Commitment for the initiative
  • Health Ministers
  • Department of Health
  • NHS Commissioning Board