

## Safe Design Of Infusion Devices And Materials



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**National Reporting and Learning Service** 

Design Council

#### DESIGN FOR PATIENT SAFETY

A SYSTEM-WIDE DESIGN-LED APPROACH TO TACKLING PATIENT SAFETY IN THE NHS

This report sets out a perspective from the world of design – based on a scoping study carried out by a research team from the Universities of Cambridge and Surrey and the Royal College of Art – to identify previously unrecognised opportunities for improved patient safety in the NHS.





## **Design For Patient Safety Series**









# Use Colours To Differentiation to Highlight Information



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#### Injection vial design





NHS National Patient Safety Agency National Reporting and Learning Service

#### Injection vial design





## Design of dispensing environment



## Size of Dispensing Label and Font

28 Medicine Name 200mg tablets Take ONE tablet THREE times a day Warning avoid alcoholic drink Take with or after food Take regularly and complete the course Mrs A. Patient (Reg.2) 12 Jul 2007 For advice 020 7089 2627 Keep out of the sight and reach of children A. Pharmacy 123 Pharmacy Street, Town, AB1 C34

70mm

35mm

Arial Bold. Font Size 10 pt Arial Bold. Font Size 12 pt Arial regular. Font Size 10 pt 28 Proprietary Name 200mg tablets Take ONE tablet THREE times a day Warning avoid alcoholic drink Take with or after food Take regularly and complete the course To be swallowed whole. Do not chew. Mrs A.Patient (Reg.2) 12 Jul 2006 A. Pharmacy For advice 020 7089 2627 Keep out of the sight and reach of children Arial Bold. Font Size 8 pt Arial regular. Font Size Arial Bold, Fonit Size 8 pt Arial regular. Font Size 8 pt Arial Bold. Font Size 10 pt Arial regular. Font Size 12 pt Arial regular. Font Size 12 pt







#### Patient Safety Incidents Involving medical devices April – August 2009 (5 months)

• Each Month:

2469 - 3641

Closer working and data sharing with MHRA

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#### Patient Safety Incidents Involving Medical Devices April – August 2009 Reported Outcomes

Death	26
Severe	89
Moderate	789
Low	2548
No Harm	11278
Total	14730

## Types of device incidents

Surgical instruments	1,452
Beds and mattresses	1,358
Infusion pumps, syringe drivers	1,202
Intravenous catheters and cannulae	338
Ventilators	338
Administration and giving sets	311
Patient monitoring equipment	302
Monitors and electrodes	294
Endoscopes and accessories	283
X-ray equipment, systems and accessories	278
Anaesthetic machines and monitors	270
Patient hoists	264

## Reported cause of incident

Failure of device / equipment	6,026	41%
Lack / unavailability of device / equipment	5,080	34%
Other	2,002	14%
User error	1,306	9%
Wrong device / equipment used	290	2%
No information	26	0
Total	14730	100

#### Human Factors – Error Types





#### Gravity infusion vs device stand



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## Mains Power







#### Use of colour and design





#### Loading administration sets







# Loading Syringe Drivers



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#### Interface consistency





## Use of ISO Symbols





#### Use of Manufacturers Symbols



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## Screen display





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### Alarms





beep

beep

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6 CED

beep

veef.

#### Alarms



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#### **Device storage**



## Screen layout / font size



Drug name and concentration Flow rate Device status (infusing/stopped/standby) Time remaining / Volume to be infused Volume infused / Total volume infused Mode of delivery - continuous, PCA, KVO Power supply (mains/battery, battery life)

– Occlusion pressure levels



## Confirmation of new settings





## Drug Libraries / Medicine Labels







#### Dose error reduction software



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## Data logging





## Identification of the medicine



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#### Rates of infusion





#### Use of coloured tubing





### The 'Universal' Connector



## 'Luer' – The Universal Connector

- Designed for IV and hypodermic use.
- Also used for neuraxial, respiratory, blood pressure monitoring devices etc.





#### Luer connector and infusion spike





Spinal (intrathecal), epidural and regional administration of medicines







# Safer spinal (intrathecal), epidural and regional devices – **Part A**

From 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples must only be performed using syringes, needles and other devices with connectors that **will not** also connect with intravenous equipment. NHS National Patient Safety Agency

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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:

by 1 April 2011



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# Safer spinal (intrathecal), epidural and regional devices – **Part B**

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

by 1 April 2013

### Incidents

- The NPSA issued Patient Safety Alert 21, Safer Use of Epidural Medicines in March 2007, with an implementation date of December 2008<sup>5</sup>.
- A further 18 low or no harm reports of wrong route errors involving epidural devices and four involving regional devices have been reported between 1 January 2008 and 31 July 2009. There have been no further reports of intravenous vinca alkaloids being administered by the spinal (intrathecal) route in the UK, but additional deaths have occurred in other countries.

#### Table 1. Number of patient safety incidents by wrong route incident type

Wrong route incident type	Number of incidents
Epidural medicine administered by the intravenous route	9
Intravenous medicine administered by the epidural route	9
Intravenous medicine administered by the regional	3
anaesthetic route	
Regional medicine administered by the intravenous route	1

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# 8

- The Problem
- The Solution
- Connectors

The Middlesigned to prevent misconnections specialised small-pore connector system. moulded from hard plastic, which is either permanently-fitted or moulded onto specific small-diameter tubular medical devices, typically needles, syringes, microbial filters, drug containers and flexible fluid-conducting tubes.

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Neurax 0.2 micron filter with 19G x 38mm needle. ATP636



B-Link Neurax Sml Syringe AT P602

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Independent Clinical Tests give 'thumbs-up' to Neurax - July 2010

via the NHS Supply

Chain or direct from

B-Link (UK) Ltd

#### more»

#### Neurax® Devices

B-Link are planning to supply the following devices from September 2010:

- non-luer syringes 1,3,5,10, 20 and 50ml . The syringes can be used either in 'slip' or 'lock' mode, by optional use of a slide-able collar;
- non-luer loss of resistance, lock and slip,7ml syringe;
- 22G-27G Quincke & 'Pencil Point' spinal needles & introducers, in various lengths plus accessories to aid diagnostic & chemotherapeutic procedures;
- 16G -18G Tuohy epidural needles, with detachable wings, together with accessories to enable infusions of local anaesthetic (e.g., catheters, filters, lines).

# Publications available on the NPSA website

 Search terms NPSA and Design for Patient Safety

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#### Surety® System for Spinal, Epidural and Regional Anaethesia - Available from November 2010

Welcome to the Surety® website.

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# (S) Surety<sub>®</sub>

Surety® is a neuraxial system designed by awardwinning UK syringe manufacturer, InterVene Limited in response to the NPSA's 'purchasing for safety' initiative for neuraxial (spinal and epidural) medical devices with safer connectors to further minimise wrong route errors.

We recognise that to achieve a quick and substantial uptake from healthcare professionals it is important to collaborate with other manufacturers. With this in mind, Surety® is available to industry partners without exception and at low cost.



#### Surety® Devices

InterVene are planning to supply the following devices from November 2010:

- Non-luer slip and lock syringes
- 1,3,5,10ml and 20ml, 60ml lock syringes;
- Non-luer loss of resistance, lock and slip,10ml syringe;
- Non-luer three way tap, drawing up filter straws and needles and a introducer needle.

#### **REGANESTH®** Spinal Needles Pencil-Point and Quincke Safer Spinal Devices with Non Luer (5), Surety. Connectors



#### NPSA Compliant Products for Spinal Anaesthesia

- · Facilitate safer practice and minimise risks to patients
- · Do not connect with intravenous equipment

TRANSMED Product Range

554\_Spinal\_SURETY\_Non\_Luer\_Connector\_GB\_0910.indd 1

- · Spinal needles with pencil-point tip and Quincke bevel
- REGANESTH® spinal needles pencil-point with non-glare and non-reflecting liquor chamber
- Quick detection of the liquor reflux due to the transparent needle hub

#### **Epidural Anaesthesia**

Safer Epidural Devices with Non Luer (S) Surety. Connectors



#### NPSA Compliant Products for Epidural Anaesthesia

- Facilitate safer practice and minimise risks to patients
- Do not connect with intravenous equipment
- · Epidural needles with Tuohy bevel in different lengths
- · For long-term anaesthesia and analgesia





Needles and device manufacturers planning to incorporate Surety® connectors

Blue Box Medical, Pajunk UK, Rocket Saesedt Medical Vygon.

#### SafeConnect Devices

B Braun Medical are planning to supply new devices from February 2011:

- a wide range of spinal needle sizes 18G to 27G, 40mm to 120mm;
- Quincke and Pencil Point bevels;
- a full range of required accessories including 5ml slip and lock syringes,

drawing up devices and protective caps for prefilled syringes;

- Ready-to-use safety packs and single items;
- Single packed items will be introduced step by step after the market launch of the packs.

#### **Devices from Becton Dickinson**

Becton Dickinson (BD) are planning to supply the following devices before April 2011: • A wide range of spinal needles with

• A wide range of spinal needles with Whitacre or Quincke tip types, various gauge sizes from 18 to 27G,

and lengths of 38 to 127mm;

• Syringes and blunt fill needles

#### **CorrectInject®** *Devices*

Smiths Medical are planning to supply the following devices:
epidural catheters, including a catheter connector, syringe, filter, filter straw and infusion adapters, by the end of 2010;
CorrectInject® safety system technology will be developed into CADD® epidural infusion systems, including yellow CADD® medication cassette reservoirs, extension sets and administration sets with bag spikes. The project schedule for the CADD® CorrectInject® System is still being determined but is targeted for the middle of 2011;

• Devices for spinal procedures are also being developed. Again the project schedule is still being determined but is targeted for early 2011.

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## **ISO TC 210**

# Small-bore connectors for liquids and gases in healthcare applications — Part 1: General Requirements

- Part 1: General Requirements
- Part 2: Connectors for breathing systems and driving gases applications
- Part 3: Connectors for enteral applications
- Part 4: Connectors for urethral and urinary applications
- Part 5: Connectors for cuff inflation applications
- Part 6: Connectors for neuraxial applications

# ISO TC210 Meeting in Seattle 14<sup>th</sup> – 17<sup>th</sup> October 201

- Review committee draft of part 6 standards proposal B-link design
- Receive presentation for potential part 6 standards proposal Surety
- Nothing on the table from Smith Medical or Becton Dickinson

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## WWW.NPSA.NHS.UK