Safe Design Of Infusion Devices And Materials

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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.

(NHS National Patient Safety Agency
National Reporting and Learning Service

Putting patient safety first)
Design For Patient Safety Series
Use Colours To Differentiation to Highlight Information

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Generic Name</th>
<th>Tablets</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Generic Name</td>
<td>Tablets</td>
<td>10 mg</td>
</tr>
<tr>
<td>28 Tablets</td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>Tablets</td>
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<tr>
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<td>Tablets</td>
<td>20 mg</td>
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<tr>
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<td></td>
<td></td>
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<tr>
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<td>Generic Name</td>
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<tr>
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<td>Generic Name</td>
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<tr>
<td>28 Tablets</td>
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</tr>
</tbody>
</table>
Injection vial design

Proprietary name
Emulsion for injection or infusion
Generic name:
Each 1ml contains 10mg of Generic Name. Also contains soybean oil refined, triglycerides medium bottled egg phosphatide, glycerol, oleic acid, hydroxide and water for injections. To be administered intravenously, subcutaneously, intramuscularly.

Proprietary name
Generic name
10mg/ml
For intravenous, intramuscular injection.
500mg
50ml
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 3C4

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 2007
A. Pharmacy For advice 020 7089 2627
Keep out of the sight and reach of children

Arial Bold, Font Size 10 pt
Arial Bold, Font Size 12 pt
Arial Regular, Font Size 10 pt
Arial Regular, Font Size 8 pt
Arial Regular, Font Size 12 pt
Design for patient safety
A guide to the design of infusion devices

Edition 1
2009
Patient Safety Incidents
Involving medical devices
April – August 2009 (5 months)

• Each Month:
  2469 – 3641

• Closer working and data sharing with MHRA
Patient Safety Incidents
Involving Medical Devices April – August 2009
Reported Outcomes

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>26</td>
</tr>
<tr>
<td>Severe</td>
<td>89</td>
</tr>
<tr>
<td>Moderate</td>
<td>789</td>
</tr>
<tr>
<td>Low</td>
<td>2548</td>
</tr>
<tr>
<td>No Harm</td>
<td>11278</td>
</tr>
<tr>
<td>Total</td>
<td>14730</td>
</tr>
</tbody>
</table>
Types of device incidents

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical instruments</td>
<td>1,452</td>
</tr>
<tr>
<td>Beds and mattresses</td>
<td>1,358</td>
</tr>
<tr>
<td>Infusion pumps, syringe drivers</td>
<td>1,202</td>
</tr>
<tr>
<td>Intravenous catheters and cannulae</td>
<td>338</td>
</tr>
<tr>
<td>Ventilators</td>
<td>338</td>
</tr>
<tr>
<td>Administration and giving sets</td>
<td>311</td>
</tr>
<tr>
<td>Patient monitoring equipment</td>
<td>302</td>
</tr>
<tr>
<td>Monitors and electrodes</td>
<td>294</td>
</tr>
<tr>
<td>Endoscopes and accessories</td>
<td>283</td>
</tr>
<tr>
<td>X-ray equipment, systems and accessories</td>
<td>278</td>
</tr>
<tr>
<td>Anaesthetic machines and monitors</td>
<td>270</td>
</tr>
<tr>
<td>Patient hoists</td>
<td>264</td>
</tr>
</tbody>
</table>
Reported cause of incident

<table>
<thead>
<tr>
<th>Cause</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure of device / equipment</td>
<td>6,026</td>
<td>41%</td>
</tr>
<tr>
<td>Lack / unavailability of device / equipment</td>
<td>5,080</td>
<td>34%</td>
</tr>
<tr>
<td>Other</td>
<td>2,002</td>
<td>14%</td>
</tr>
<tr>
<td>User error</td>
<td>1,306</td>
<td>9%</td>
</tr>
<tr>
<td>Wrong device / equipment used</td>
<td>290</td>
<td>2%</td>
</tr>
<tr>
<td>No information</td>
<td>26</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14730</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
Human Factors – Error Types

Basic error types

- Violations
- Mistakes
- Lapses
- Slips

Intended actions

- Routine Reasoned
- Rule & Knowledge Based errors

Unsafe acts

- Reckless & Malicious
- Skill based errors
  - Memory failures
  - Attentional failures

Unintended actions
Gravity infusion vs device stand
Mains Power
Use of colour and design
Loading administration sets
Loading Syringe Drivers
Keyboard Layout
Multifunction buttons

\[ \text{e.g. } \begin{array}{c} \text{F} + \text{7} \end{array} \Rightarrow \text{Bolus function} \]
Interface consistency
Use of ISO Symbols

- Infusion status
- Injection syringe
- Infusion bottle
- Trend information
- Manual control
- Handheld switch
- Variability
- Variability in steps
- Patient
- Nurse
- Lighting
- Do not reuse
- Battery check
- Power plug
- Bell cancel
- Sound muting
- On
- Off
- Start
- Stop
Use of Manufacturers Symbols
Screen display
Alarms
Alarms

Putting patient safety first
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

Choosing reverts to main screen. No indication of alarm level selected.

Main screen

OCCLUSION ALARM
- HIGH
- MEDIUM
- LOW

OCCLUSION ALARM
- HIGH
- MEDIUM
- LOW

High alarm sensitivity selected.

Main screen

Putting patient safety first
Drug Libraries / Medicine Labels
Dose error reduction software

Start up screen
- Rate: 100 mL/HR
- Volume: 250 mL

Do you want to use Drugsure?
- No
- Yes

Drugsure:
- Dobutamine 5mg/ml
- Dopamine 4mg/ml
- Heparin Sodium 1000units/ml
- Midazolam 1mg/ml

Heparin Sodium:
- Volume: 50ml
- Time: 12hr 30min
- Rate: 4000 units/hr
- Mode:

putting patient safety first
Data logging
Identification of the medicine
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.

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
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

- 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

<table>
<thead>
<tr>
<th>Wrong route incident type</th>
<th>Number of incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural medicine administered by the intravenous route</td>
<td>9</td>
</tr>
<tr>
<td>Intravenous medicine administered by the epidural route</td>
<td>9</td>
</tr>
<tr>
<td>Intravenous medicine administered by the regional anaesthetic route</td>
<td>3</td>
</tr>
<tr>
<td>Regional medicine administered by the intravenous route</td>
<td>1</td>
</tr>
</tbody>
</table>
Neurax is available via the NHS Supply Chain or direct from B-Link (UK) Ltd.
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
Welcome to the Surety® website.

Surety® is a neuraxial system designed by award-winning 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 'S.Surety' Connectors

Epidural Anaesthesia
Safer Epidural Devices with Non Luer ‘S.Surety’ Connectors

NPSA Compliant Products for Spinal Anaesthesia
- Facilitate safer practice and minimise risks to patients
- Do not connect with intravenous equipment
- Spinal needles with pencil-point tip and Quincke bevel
- REGANESTH® spinal needles, pencil-point with non-glare and non-reflecting lumen chamber
- Quick detection of the liquor reflux due to the transparent needle hub

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

Putting patient safety first
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 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.
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
14th – 17th 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