Draft Patient Safety Alert

Non-Luer Spinal (Intrathecal) Devices For Chemotherapy and Lumbar Puncture

Draft supporting information

November 2013

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Document Status

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NOTE: This supporting information is intended to be read with the Draft Patient Safety Alert. Non-Luer Spinal (Intrathecal) Devices For Chemotherapy and Lumbar Puncture. Issued November 2013

Link to NHS England web page:
https://www.engage.england.nhs.uk/consultation/f96c16f5

Background

Following incidents of death or paralysis as a result of mal-administered intravenous vincristine by the spinal (intrathecal) route, the elimination of harm from this cause was one of the four specific targets in the DH Report *An Organisation with a Memory* (2000)[1] .The publication of two reports relating to the prevention of intrathecal medication errors in 2001[2 - 3] led the DH to issue national guidance for safe administration of intrathecal chemotherapy[4-7].

In order to further minimise risks of wrong route administration, The National Patient Safety Agency issued two Alerts (2009, 2011) recommending a purchasing for safety initiative where medical devices with connectors that cannot connect with intravenous Luer or infusion devices connectors for spinal (intrathecal), epidural and regional clinical procedures, when suitable devices became available [8-9]. Target implementation dates of 1st April 2012 for spinal (intrathecal) bolus (Part A), and 1st April 2013 for epidural and infusion (Part B) devices, were identified.

It was recognised in these Alerts that that devices with new design connectors would have to be manufactured and supplied by industry before the NHS could comply with the guidance. NHS organisations were recommended to record the continued use of non-compliant devices in the organisation's risk register, ensure additional safety precautions were taken and introduce suitable safer devices into practice as soon as they became available.

By November 2013, approximately 70 NHS Trusts in England have introduced non-Luer neuraxial devices into practice and approximately 300,000 spinal needles have been purchased by the NHS in England.

Although the NPSA worked very closely with the medical devices industry, when drafting the Patient Safety Alerts, the introduction of complete ranges of new medical devices and supporting test information to meet the requirements identified in the Alerts has taken longer than planned.

1. Range of non-Luer devices required for spinal (intrathecal) and lumbar puncture procedures

The External Reference Group On Neuraxial Devices advised the NPSA on the range of devices required for spinal procedures to enable compliance with the Part A Alert. These details were published in the Neuraxial Update Newsletter Issue 3 (October 2011)[10] and are shown below:

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

There is now a complete range of non-Luer devices with the Surety design of connectors available from a range of needle suppliers and one syringe manufacturer. (Blue Box Medical, B Braun, Intervene, Pajunk, Rocket Medical, Sarstedt, Vygon).

There are incomplete ranges of non-Luer devices with the Correctinject connector from Smiths Medical and UniVia from Becton Dickinson.

With a full range of non-Luer devices for Intrathecal Chemotherapy and Lumbar Puncture procedures now on the market, NHS Trusts should be aware that non-compliance in using these devices could be a breach of Care Quality Commission Standards and could lead to regulatory action by other agencies.

2. Independent test information on non-Luer devices

In the Neuraxial Update Newsletter Issues 3 (October 2011)[10] details of recommended independent tests for new non-Luer connector designs were identified. Details of physical, microbiological and clinical evaluations were identified.

The following independent test information is available:

Physical leak tests

Results of tests undertaken by the Surgical Materials Test Laboratory, Bridgend South Wales[11].

- Correctinject connector devices – Smiths Medical – Pass
- Surety connector devices – Intervene, Pajunk, Sarstedt - Pass
- Univia connector device – Becton Dickinson - Pass

Microbiological tests

Results of tests undertaken by the Surgical Materials Test Laboratory, Bridgend South Wales[11].

- Correctinject devices - Pass
- Surety connector devices – some failures – a investigation report has been produced

Members of the Welsh NHS team undertaking the microbiological testing of the devices have concerns about Intervene documents investigating the causes of the microbiology failures with Surety connectors and the conclusions drawn as a result of it [11].

Results of test commissioned by the Pharmaceutical Aseptic Services Group (PASG)

- Correctinject devices – Smiths Medical – Pass
- Surety connector devices - Pass

The NHS Pharmaceutical Aseptic Services Group (PASG) (England) has reviewed the available data relating to use of non-luer neuraxial devices as storage containers for injectable medicines[12]:

> *'Dye-intrusion integrity testing and other studies have demonstrated that locking varieties of the two brands tested, Smiths Medical (CorrectInject) and Intervene (Surety) - are capable of providing a robust system for the*

preparation, transport, storage and administration of chemotherapy and other drugs to be given by the spinal and intrathecal route, for up to 7 days.'

'Further, an investigation[8] (overseen by PASG) into the failure of earlier microbiological integrity testing with some Surety syringes has shown no residual concerns regarding these devices provided that specific capping instructions are followed. The report gives detailed instructions for pharmacy staff on filling and capping these syringes and separate manufacturer's instructions are available.'

As a result, Pharmacy Aseptic Units preparing doses for spinal and intrathecal administration, working with clinical colleagues responsible for the administration process, nursing staff and procurement departments, should consider undertaking a process of managed change away from luer-compatible devices towards the new safer-connecting devices.

PASG recommends that locking varieties of the two brands listed above are suitable for storage of capped doses, when used according to the manufacturers' instructions, to the best of the information available at this time.

Clinical tests

Kinsella et al undertook a clinical evaluation of four non-Luer spinal needle and syringe systems in 2012[13].

Neuraxial devices with Surety and Correctinject non-luer connectors from four manufacturers were evaluated in addition to Luer devices from one manufacturer. Non-Luer devices were associated with more qualitative problems compared with the Luer devices, for example, poor feel of dural puncture, poor observation of cerebrospinal fluid in the hub and connection problem of the syringe to the spinal needle There were also more frequent failure to achieve the spinal injection due to equipment-related cause. The non-Luer evaluations were rated with satisfaction worse than the usual Luer device used by the clinician involved in the evaluation.

The Kinsella evaluation study design has been criticised by Toft and Cousins[14] who suggested that findings of dissatisfaction with devices in the evaluation, such as poor feel of tissue planes, needle flexibility and observation of cerebrospinal fluid, may be due to variables that were not adequately controlled for and not due to non-Luer connectors. They described a more appropriate study design including both Luer and non-Luer devices from all manufacturers.

Seven non-Luer spinal needles were evaluated in a study by Sharpe et al in 2013[15]. The time to see and collect simulated cerebrospinal fluid was measured and clinicians scored needle quality using a standardised questionnaire. The study found that:

'*the mean times to see cerebrospinal fluid varied in the lateral position and in the sitting position. Satisfaction scores in 205 needle evaluations were recorded. The median satisfaction scores for needles and overall non-Luer equipment were higher this evaluation than those seen in Kinsella et al.'s study. Three of the four Surety-based systems had median satisfaction scores of 9 out of 10 with the BBraun system showing satisfaction scores extremely close to the figures Kinsella et al. report for current Luer lock systems.'*

'Although we have demonstrated some differences between the systems we tested, these must be seen in context, as the clinical significance is not obvious. Over 70% of assessments were still in favour of using even the lowest ranking needle again.'

Susnerwala et compared the number of (i) obstetric spinals administered, (ii) failed blocks, (iii) failed insertions, and (iv) inadequate blocks over two 12-month periods, before and after the introduction of Univia non-Luer spinal needles in an obstetric unit in a District General Hospital[16].

Approximately 703 non-Luer spinal needles were used in 12 months. There were no significant differences in failure rates between the use of Luer and non-Luer spinal device needle kits. Overall the introduction of the non-Luer devices in the obstetric unit had been received with a high level of satisfaction by clinical uses.

Cross connection

In the Neuraxial Update Newsletter Issue 2 February 2011[17] the following information appeared in the frequently asked question section:

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

'Response: 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 Alerts recommends the use of non-Luer connector designs to prevent the specified wrong route errors with intravenous devices. The objective of purchasing for safety initiative is that equipment is selected that does not allow accidental cross-connection of neuraxial, intravenous and enteral equipment when used in clinical configurations.

The Surgical Materials Test Laboratory has undertaken cross connection studies and found the following[11]

Surety syringe (female) to Intravenous syringe (male) cross connection

Surety syringe (female) to Vygon Intrasafe 2 (male) cross connection

Surety syringe (female) to Medicina Enteral feed tube (male) cross connections

All the above cross connections are not in contravention of the NPSA Alerts.

Smiths Medical CorrectInject Syringe (Male) to Luer Lock Spinal Needle Introducer (female)

The NPSA Issued guidance that spinal introducer needles should no longer have a female Luer connector to avoid the risk Luer syringes, and in this case Correctinject syringes, being connected.

Smiths Medical CorrectInject Syringe (Male) to Terumo Luer Lock Cannula (female)

This cross connection is not in compliance with the guidance in the NPSA Alert and introduces the risk of wrong route connection.

3. New ISO standard non-Luer connector design

There has not been a formal communication from the ISO Standards Organisation on when a new design standard for a neuraxial connector will be completed and published.

There has been an un-official timeline published by the Association for the Advancement of Medical Instruments[18].

The timeline describes a process that will produce an ISO standard for neuraxial connectors by February 2015

However, the following concerns have been identified with this unofficial timeline:

- There have been many previous delays involved in the development of this standard, and further delays may occur.
- The date for the publication of an ISO Standard does not mean that a full range of neuraxial devices with this new connector will be available on the market in the UK by this date.
- Additional independent evaluations of devices with ISO standard connectors are likely to be required e.g. microbiology testing of syringe caps, and additional clinical simulation tests, before NHS organisations may be willing to introduce these new devices into practice. This may result in further delays,
- Work has yet to begin on developing an ISO standard design to replace the intravenous spike connector for neuraxial infusions, so a full range of devices with ISO connectors to enable full compliance with NPSA alerts is very unlikely to be available in 2015.

For this reason, the benefits to patient safety of using non-Luer devices on the market in the UK now, should not be ignored by NHS organisations.

In the event of a serious wrong route administration error involving a neuraxial device or medicine, NHS organisations not using a commercially available non-Luer device that may have prevented or minimised the resulting harm would have to provide detailed information why such a device was not used in practice.

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