THE INTRODUCTION OF NEW NEURAXIAL CONNECTORS INTO THE NHS

A Position Statement from:

The Association of Anaesthetists of Great Britain and Ireland

The Royal College of Anaesthetists

The Obstetric Anaesthetists' Association

Regional Anaesthesia UK

The Association of Paediatric Anaesthetists of Great Britain and Ireland

Royal College of Anaesthetists Patient Liaison Group

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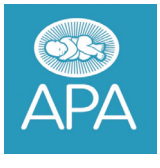
The Association of Anaesthetists of Great Britain & Ireland

The Royal College of Anaesthetists



The Introduction of New Neuraxial Connectors into the NHS

A Position Statement from the Association of Anaesthetists of Great Britain and Ireland, the Royal College of Anaesthetists, the Obstetric Anaesthetists' Association, Regional Anaesthesia UK, the Association of Paediatric Anaesthetists of Great Britain and Ireland and the Royal College of Anaesthetists Patient Liaison Group - updated 25th October 2011

Executive Summary

1. The elected Councils of our specialty membership organisations and our patient liaison representatives believe that the current process of introducing new spinal needles and connectors into the NHS without published independent evaluation in the clinical setting may increase risks to patients undergoing spinal anaesthesia.

2. Centralised or other published independent testing would remove the difficulties with this process, but is not planned in England because of concerns about competition law. Data from the national assessment in Wales will become available in 2012 and would be useful to guide clinicians in England in their adoption of new needles and connectors.

3. If departments in England wish to test new connectors in accordance with NPSA recommendations, this should be done in a robust and organised way with results being published so that information is available to the whole NHS. We do not believe that informal assessment by a few individuals trying out a few needles is of benefit to patients or the NHS.

4. We remain of the view that a single, satisfactory, tested design of neuraxial and regional anaesthesia connector should be introduced into the UK NHS and private healthcare. The specialty has always supported this. We recognise the major investment by manufacturers but we question whether there is any overall benefit for patients in the NHS if spinal anaesthesia is performed with multiple, non-standard connectors.

5. We recognise the need to complete the work to improve the safety of intrathecal chemotherapy injections, but in anaesthesia the risk of infusion/injection of fatal doses of local anaesthetics intravenously is greater.

6. We recommend that decisions about spinal, epidural and regional anaesthesia connectors are made at the same time in a co-ordinated manner after formal independent clinical testing in patients.

Background

In 2002 the Department of Health issued a call to manufacturers to produce a new non-Luer connector to prevent wrong route intrathecal (spinal) injection errors. The background to this work is well documented and followed reports into the tragic death of Wayne Jowett resulting from the injection of intrathecal vincristine. [1,2,3]

In 2009 the NPSA issued a Safety Alert that required all hospitals in England and Wales to purchase new equipment to ensure that all spinal injections and lumbar punctures are performed using equipment with non-Luer connectors that will not connect with intravenous equipment.

The implementation date for this initiative was originally April 2011 but after pressure from the specialty, this was delayed to April 2012 as new devices had not been brought to market, nor had they undergone clinical evaluation in patients. At present up to 12 companies are planning to produce equipment using around 5 new non-Luer connector designs. The ISO standard for new non-Luer connections has not been published and is not likely to be developed for several years.

The pathways, systems and training for the administration of chemotherapy have been completely redesigned since 2001, and there has not been another case of wrong route chemotherapy in the UK. Further accidental intrathecal injection of vincristine in the NHS would require exceptional violation of multiple steps in safety procedures.

New spinal needle connectors for anaesthesia

- Spinal anaesthesia is currently performed using needles that have a proven, safe, effective connector. There is one universal system throughout the NHS.

- Spinal anaesthesia is a skilled task. In some patients, needle insertion may prove difficult and require several attempts. Once inserted into the intrathecal space, any difficulty attaching a syringe to the connector risks displacing the needle. Needles and connectors tested under laboratory conditions may perform differently in the clinical setting.

- Around 370,000 patients per year undergo spinal anaesthesia in UK. If new connectors do not work as effectively as existing ones, patients may face an increased risk of failed spinal anaesthesia. The level of this risk cannot be identified as the devices have not been formally assessed in a clinical setting with results available in the public domain. In early clinical testing one prototype was associated with a higher incidence of failed spinals. [4]

- In obstetric practice, pregnant patients undergoing emergency spinal anaesthesia will potentially be placed at even greater risk, as a failed spinal will require administration of a general anaesthetic. General anaesthesia is known to carry a greater risk for the mother and child than a spinal anaesthetic.

- The only published peer reviewed evidence suggests that new connectors perform less well than the standard Luer. The report concluded “before

introducing any non-Luer device into widespread use, independent, formal evaluation should be carried out".[5]

- The NHS in Wales plans bench testing of the new connectors followed by clinical evaluation to select a single connector as a part of a national procurement process. The NHS in England is introducing new neuraxial connectors without centralised testing, allowing market forces to determine which connectors are used. Market presence may drive purchasing decisions rather than evidence of clinical efficacy and safety.

- Drugs for spinal anaesthesia are drawn up just before administration. Without pre-filled syringes, the new connection systems will not eliminate injection errors, and will not improve the safety of spinal anaesthesia. A systems solution, such as double-checking, as has been found to be effective for intrathecal injection procedures, might be more effective.

Why a new connector is required in anaesthesia

- In anaesthesia a more urgent requirement is to prevent intravenous administration of local anaesthetic drugs intended for epidural and regional block, either in the form of direct injection or infusion. This requires a solution at various levels including infusion bags, intravenous lines, syringes and connectors.

- The only published peer reviewed assessment of new devices suggests that clinicians may prefer a different solution for spinal needles compared to epidural needles[5].

- A single, new, fully tested neuraxial connector with dedicated regional anaesthesia syringes and infusions will be a step forward in safety for UK patients. Ideally, a single connector system would be purchased and an ISO standard would apply.

Introducing new connectors into clinical practice

The NPSA is conducting a series of "Road Shows" to allow clinicians to familiarise themselves with the new connection systems, and recommends that the new systems are then tried out on patients in the clinical setting to assess the best device for each hospital. These local assessments may be the first occasion on which these new devices are used in patients.

The NPSA recommends only one type of new neuraxial connector per hospital to avoid multiple connectors and syringes being required. Mistakes in the supply chain ordering "spinal" needles have already occurred. As there are different dates for implementation of spinal and epidural/regional anaesthesia connectors, the practice of combined epidural and spinal anaesthesia in obstetrics may be complicated by requiring equipment from different manufacturers, which may be partly incompatible.
The introduction of the new connectors is a logistics challenge and there must be effective change management in the hospital encompassing all relevant processes, staff and departments, including procurement. Manufacturers must take some

responsibility in assisting procurement staff to avoid mistakes.
Devices are different from drugs - it would normally be considered unethical to test new drugs on patients without publication of the appropriate trial data; this is not the case for the new neuraxial devices under consideration. These devices are not pharmaceuticals, and as Class III CE marked devices may be brought to market without independent evaluation in patients.

Training will need to be undertaken in each hospital and trainees may be asked to use different equipment during their rotations. This may increase risk to patients.

Many colleagues feel that in the absence of any published independent testing of connectors, replacement of the Luer system without evidence of improved safety provides no benefit to patients undergoing anaesthesia. However, this is at odds with the NPSA mandate.

There is a system of post-market surveillance by the MHRA should safety issues arise, but the NPSA is taking the lead for dissemination of incidents relating to the new neuraxial connectors. This is a system that we believe may be compromised due to the current uncertainty about critical incident reporting and analysis in the NHS, as the NPSA is soon to be abolished and the future of the NRLS has yet to be announced.

Professor Toft (Chair NPSA Neuraxial External Reference Group) has clearly stated on a number of occasions that anaesthetists should not be compelled to use equipment that they consider may be unsatisfactory. However, this is the situation towards which we are rapidly heading in the NHS in England. Clinicians may wish to seek advice from their hospital clinical risk management team and may wish to use the risk register if they consider that patient safety might be compromised by the processes demanded by the NPSA.

Dr Iain H Wilson
President, Association of Anaesthetists of Great Britain and Ireland

Dr Pete Nightingale
President, Royal College of Anaesthetists

Mr Archie Naughton
Lay Member, Patient Liaison Group of the RCoA

Dr David Bogod
President, Obstetric Anaesthetists Association

Dr Nick Scott
President, Regional Anaesthesia - UK

Dr Kathy Wilkinson
President, Association of Paediatric Anaesthetists of Great Britain and Ireland

Explanatory Notes

The Luer Connector

This 6 degree taper connector was introduced into clinical practice over 100 years ago and owes its success to the shape of the taper, which allows easy connection and disconnection and a good seal for injecting drugs. This is of particular importance in spinal anaesthesia when any movement of the needle during syringe attachment or detachment risks failed anaesthesia.

Vincristine

Vincristine is an anti-cancer drug designed for intravenous use; it is fatal when administered intrathecally. A total of 58 accidents due to accidental intrathecal injection have been reported internationally. In the UK, safety procedures were further updated in 2008 and the NPSA issued a Rapid Response Report requiring vincristine to be produced in 50-ml minibags for adults and adolescents. The new guidance allows only certified staff to carry out chemotherapy injections and intrathecal injections are never given at the same time or in the same location as intravenous injections. An estimated 15,000 doses of intrathecal chemotherapy are given in the NHS each year and there have been no further reports of wrong route vincristine injections in the NHS since 2001.

Wrong route intravenous local anaesthetic drugs

In parallel with the concerns about wrong route vincristine (now diminished due to system redesign), there have also been fatalities due to the intravenous injection or infusion of local anaesthetic drugs intended for epidural use (or nerve block catheters). This remains a concern in anaesthetic practice, when local anaesthetics may be injected directly intravenously or a bag of local anaesthetic agent connected to an intravenous infusion set as there is a common ‘spike’ connector for both types of fluid container.

Drawing up drugs in anaesthesia practice

In anaesthesia practice, a few specialised infusion drugs are prepared by the pharmacy and are issued in pre-prepared syringes but, in general, the anaesthetist draws up drugs immediately before injection, which is in line with DH recommendations. At present, ensuring that the correct drug is administered by the intended route depends upon on properly performed checking procedures and correct labelling, not the use of a specific connector. Pre-preparation of multiple syringes ahead of use risks generating confusion.

Spinal Anaesthesia in UK

In the NHS the NAP3 study demonstrated that around 370,000 spinal injections are performed in anaesthesia each year [6]. Many of these are in obstetrics in which spinal anaesthetics are often carried out as an emergency procedure to allow Caesarean section. The design and functionality of the needles and connections are crucial. Drugs for intrathecal injection are drawn up, and sometimes mixed at the point of delivery in the manner described above. There were no wrong route spinal events reported to this year-long project. [7]

Systems redesign

Systems, protocols and checklists have been successfully applied to intrathecal chemotherapy with excellent results, but not applied to anaesthetic intrathecal or regional procedures.

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