Neuraxial Connector – Anaesthesia Risk Assessment

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 due to the injection of intrathecal vincristine. In 2009 the NPSA issued a Safety Alert that requires all hospitals in England and Wales to purchase new equipment to ensure that all spinal injections and lumbar puncture samples 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 testing. At present there are up to 12 companies planning to produce equipment using new non-Luer connector designs. The ISO standard for new non-Luer connections has not been published and is not likely to be for several years.

Risk assessment

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

- Due to extensive systems redesign around the injection of vincristine, a further wrong route injection in the NHS would require exceptional violation of multiple steps in safety procedures.

- In anaesthesia efforts should be made to prevent intravenous administration of local anaesthetics drugs. This requires a solution at various levels including infusion bags, iv lines, syringes and connectors. A simple connector change for spinal needles does not prevent this hazard.

- Whilst the NHS in Wales plans bench testing of the new connectors followed by clinical evaluation to select a single national connector, in England and Scotland the NHS is introducing new neuraxial connections without centralised testing. If the new connectors do not work as efficiently as the current Luers, this will expose > 370,000 patients / year to spinal injections with a potential risk of failure of anaesthesia. The level of this risk cannot be identified as the devices have not been tested, but the incidence of failed spinals was found to be unacceptable during testing of prototypes.

- The only published evidence around the efficacy of the new connection systems demonstrated that the new connectors were not as efficient as the Luer, and some cross-connectability still existed.

- In obstetric practice, pregnant patients undergoing emergency spinal anaesthesia with untested devices will be at particular risk, as a failed spinal will require administration of a general anaesthetic that is known to carry a greater risk for the mother and child than a spinal anaesthetic.
The new connection system may not eliminate injection errors in the anaesthetic room as the anaesthetist is required to draw up drugs just prior to administration. A systems solution, similar such as double-checking, as in the intrathecal procedures, could be more effective.

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 may easily occur. As there are different dates for implementation of spinal and epidural/regional anaesthesia connectors, the practice of combined epidural and spinal anaesthesia in obstetrics will be complicated by requiring equipment from different manufacturers which may be partly incompatible.

Suitable equipment for paediatric practice will need to be available (spinal needles, epidural needles and needles for caudal injection (currently performed with intravenous cannulae or needles).

It would normally be considered unethical to test new drugs on patients without publication of the appropriate trial data; this does not appear to be the case for the new neuraxial devices under consideration. Many colleagues feel that in the absence of any laboratory assessment of connectors testing on patients is unethical. However this is not universally accepted given the NPSA mandate.

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 an ISO standard would apply. At present this is not what is to be delivered.

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. This however, is the situation that is developing in the NHS in England and Scotland.

Since the original decision to introduce a new neuraxial connection was taken, considerable learning from the NPSA NRLS has taken place and demonstrates that the risks in anaesthesia require more consideration than a change to the connector.

There is a system of post-market surveillance should safety issues arise, but this system which is already inadequate, could become dangerously so due to the current uncertainty about critical incident reporting and analysis in the NHS.

**Conclusion**

The elected Councils of our specialty membership organisations, and our patient liaison representatives, believe that the process of introducing untested spinal needles and connectors into the NHS will increase risks to patients undergoing anaesthesia.

Centralised testing would remove all difficulties with this process, but is not planned in England and Scotland. Data from the national assessment in Wales will become available in 2012 and should be used to guide clinicians in England and Wales in their adoption of new needles and connectors. Timelines should take account of this.
If departments in England wish to test new connectors following the NPSA mandate, this should be done in a robust and organised way with results being collected centrally, so that information is available to the whole NHS. Trying out a few needles at a time in the hands of a few individuals is not of benefit to patients, and we cannot endorse this approach. Many anaesthetists have concerns over the ethics of this process.

When a single satisfactory design of neuraxial connector is identified, it should be introduced into all UK NHS and private healthcare. The specialty has always supported this. We question whether there is any overall benefit for patients receiving anaesthesia with multiple, non-standard connectors.

In anaesthesia the more urgent need is to identify and adopt ways to prevent infusion / injection of fatal doses of local anaesthetics intravenously. This requires an equal urgency and level of consideration.

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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 where any movement of the needle during syringe attachment / removal risks failed anaesthesia.

Wrong route 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 re-design), there have also been fatalities due to intravenous injection / infusion of local anaesthetic drugs intended for epidural use (or nerve block catheter). This remains a concern in anaesthetic practice, where local anaesthetics may be injected directly intravenously or a bag of local anaesthetic agent connected intravenously as there is a common 'spike' connector for both types of fluid container.

**Drawing up drugs in anaesthesia practice**

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

**Neuraxial (spinal) injections in anaesthesia**

In the NHS the NAP3 study demonstrated that around 370,000 spinal injections are performed in anaesthesia each year. Many of these are in obstetrics where 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.

**New neuraxial connectors**

The new systems have taken a long time to develop and during preliminary testing a number of problems were detected, which manufacturers believe are resolved. In the NHS, only Wales plans any kind of centralized testing to identify the most appropriate device to replace the Luer connector on a national scale. The NHS in England has been instructed by the NPSA to introduce new systems into clinical practice by local testing on patients to select the most satisfactory connector for each Trust. This plan will result in multiple connectors throughout the country, and if supply problems occur, in individual hospitals.

Since the needles are not being altered, initial testing of the new neuraxial connectors could be performed appropriately in a laboratory setting (as planned in Wales).

**Systems redesign**

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


