NATIONAL PATIENT SAFETY AGENCY

Recommended Technical And Usability Test Results On Neuraxial Devices With Safer Connectors For Purchasers November 2010

Introduction

The NPSA recommends that medical device suppliers should provide the healthcare purchasers with independent technical and usability test results on neuraxial devices that will assist the procurement process for safer neuraxial devices described in the NPSA Patient Safety Alert on *Safer spinal, epidural and regional anaesthesia devices Parts A & B issued in November 2009.*[1]

Cook et al undertook a simulation-based evaluation of two proposed alternatives to Luer devices for use in neuraxial procedures.[2] Their conclusion was that before introducing any non-Luer device into widespread use, independent formal evaluation should be carried out.

An editorial in the same journal supported this recommendation.[3] It also reminded readers that when introducing new equipment to improve patient safety we should be mindful of Liam Donaldson's comment in his report of 2002: 'We need to be certain that any potential new design solution is rigorously tested and, crucially, that by introducing new equipment to prevent one specific type of error, we do not, in turn, introduce new unforeseen risks to patients'.[4]

This document provides details of independent tests on neuraxial devices with safer connectors that medical devices suppliers should arrange with independent centres. These tests are not mandatory however, it is recommended that the results of these technical and usability tests are supplied to healthcare purchasers to further assist them with their purchasing decisions.

Information from two types of tests should be provided, 1) laboratory based, and 2) based on clinical simulation.

The recommended laboratory tests should be based on the draft ISO standard *ISO/IEC CD 80369-6:*

> *Small-bore connectors for liquids and gases in healthcare applications – Connectors for neuraxial applications*.

Tests for verifying non-inter-connectable characteristics should also be undertaken to the requirements listed in the draft *ISO/DIS 80369- 1:2009:*

> *Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements: Annex B Mechanical tests for verifying non-interconnectable characteristics.*

The rationale behind these tests is that they are based on methods shown to be relevant and useful for assessing key performance characteristics of Luer connectors. Some modifications have been made in the light of experience with the

Luer tests and the additional functionality required of non-Luer compatible connectors, such as cross-connectability.

NOTE: The selection of the various forces involved, such as axial and torque have been based on the original Luer standard, and modified by the ISO working groups if necessary. It is quite possible that these will change as the standard is developed.

2. Laboratory Tests

Performance Requirements (*ISO/IEC CD 80369-6 monograph 6*)

Due to the absence of reference connectors at present, the *male* and *female* neuraxial connectors themselves should be used as their own reference i.e. *male* and *female* neuraxial connectors should be fitted together under a specific axial and torque as specified in each of the monographs then tested as a complete assembly.

Testing should be performed at temperatures within the range of 15-30°C at a relative humidity between 25-65%.

Security of Connection of small-bore connectors for neuraxial applications (ISO/IEC CD 80369-6 monograph 6.1)

Security of the assembled connectors (*ISO/IEC CD 80369-6 monograph 6.1.1*)

The draft standard states that connectors should be assembled using an axial (27.5 ±0.5N) and torque (0.12 ±0.02Nm), then left for 1 hour. An increasing axial force (10N/s up to 35N+- 0.5N) should then be applied in a direction away from the assembly applied and maintained for 10 seconds.

The connectors should withstand an axial distraction force of 35N.

Security of the collar (*ISO/IEC CD 80369-6 monograph 6.1.2*)

Where the *male* connector has either a fixed or floating collar, it is recommended that the collar should remain attached to the *female* connector during an unscrewing torque of 0.02Nm.

a) Fixed Collars

Assembly of connectors using an axial (27.5 ±0.5N) and torque (0.12 ±0.02Nm) to the connector collar.

b) Floating Collars

Assembly of connectors using an axial (27.5 ±0.5N) and torque (0.12 ±0.02Nm) to the body of the connector.

It is recommended that after 1 hour apply an unscrewing torque of 0.02Nm to the collar of the *male* connector and maintain for 5-10 seconds. Force should not be applied in any other direction.

Disconnection of small-bore connectors for neuraxial applications (ISO/IEC CD 80369-6 monograph 6.2)

Ease of unscrewing of male connectors with a fixed or floating collar (*ISO/IEC CD 80369-6 monograph 6.2.1*)

The *male* collar should unscrew when a torque of 0.24Nm is applied to it.

The connectors should be assembled using an axial (27.5 ±0.5N) and torque (0.12 ±0.02Nm). After 1 hour, apply an unscrewing torque of 0.24 ±0.02Nm to the collar should enable the collar to unscrew.

Maximum separation force for male connectors either without a collar or with a floating collar (*ISO/IEC CD 80369-6 monograph 6.2.2*)

The connector assembly should detach when an axial distraction force of 20.0N is applied whilst an unscrewing torque of 0.24Nm is applied to the body of the *male* connector.

The connectors should be assembled using an axial (27.5 ±0.5N) and torque (0.12 ±0.02Nm) to the body of the *male* connector. The floating collar, if fitted, should not be engaged.

After 1 hour, with the *female* fitting in a fixed position, an axial force of 20 ±0.5N should be applied to the *male* connector in a direction away from the *female* connector whilst applying a torque of 0.24 ±0.02Nm to the body of the *male* connector. Verify that the *male* connector separated from the reference female connector.

Ease of unscrewing of female connectors (*ISO/IEC CD 80369-6 monograph 6.2.3*)

The connector assembly shall unscrew when a torque of 0.24Nm is applied to it.

Assemble the connectors using an axial (27.5 ±0.5N) and whilst applying a torque of (0.12 ±0.02Nm). After 1 hour, with the *male* fitting in a fixed position, apply an unscrewing torque of 0.24 ±0.02Nm to the *female* connector. Verify that the *female* connector begins to unscrew.

Leakage from small-bore connectors for neuraxial applications (ISO/IEC CD 80369-6 monograph 6.3)

Positive-pressure liquid leakage (*ISO/IEC CD 80369-6 monograph 6.3.1*)

There should be no leakage sufficient to form a falling drop from the test connectors at the pressure of 300kPa.

Assemble the *male* connector to the *female* connector using an axial (27.5 ±0.5N) and whilst applying a tightening torque (0.12 ±0.02Nm) to the body of the *male*. For connectors with a floating collar, engage the collar and tighten to the torque of 0.12 ±0.02Nm.

After 48 hours, introduce water into the assembly and expel air. With the axis of the assembled connectors horizontal, seal the assembly outlet and ensure that the assembly is dry. Bring the internal water pressure to 300-330kPa and maintain for at least 30s. Verify that a drop of water has not fallen from the assembly within the 30 seconds.

Sub-atmospheric-pressure air leakage test (*ISO/IEC CD 80369-6 monograph 6.3.2*)

There should be no leakage of air through the connectors at a sub-atmospheric pressure of 4.0kPa.

Assemble the connectors using an axial (27.5 ±0.5N) whilst applying a torque (0.12 ±0.02Nm) to the body of the *male* connector. For connectors with a floating collar, engage the collar and tighten to the torque of 0.12 ±0.02Nm.

After 48 hours, seal the assembly outlet. Assemble the connectors to a stop-valve in a leak proof manner. Create a sub-atmospheric pressure of 4.0 ±0.1kPa and close the stop-valve. Wait for 15 ±1 seconds. Verify that the sub-atmospheric pressure has not changed by more than 0.4kPa.

IMPORTANT: This monograph is under consideration for review at present. It is recommended that manufacturers contact members of the ISO 210 Neuraxial Working Group before commissioning this test.

Ease of engagement of thread forms of small-bore connectors for neuraxial applications (ISO/IEC CD 80369-6 monograph 6.4)

If the connector has, or is intended to be used with, a fixed or floating thread collar, it is recommended that a satisfactory engagement should be achieved by applying a torque of 0.08Nm to the connectors under test.

Engage the thread of the *male* connector to the *female*. Apply a tightening torque of 0.08 ± 0.01Nm to the *male* connector. Verify that the body of the *female* connector or the collar of the *male* connector rotates.

Mechanical tests for verifying non-interconnectable characteristics (*ISO/IEC CD 80369-1 Annex B*)

This Annex of the draft standard specifies the criteria and test methods to be used to obtain objective evidence to demonstrate non-interconnectable characteristics between a small-bore connector being evaluated and the other connectors likely to be found in the patient environment.

A non-interconnectable small-bore connector should not appear to provide a secure connection when forcefully assembled to any surface of the components , and should easily disengage from each small-bore connector and its parts of every other application category specified in *ISO 80369* and the nipples of *EN 13544-2:2002 - Respiratory therapy equipment. Tubing and connectors.*

Condition the connectors to be assembled at 23 ±2°C and a relative humidity of 50 ± 5 % for not less than 1 h. Assemble the small-bore neuraxial connector to the test connector by applying an axial force at a rate of approximately 10 N/s that does not

visibly damage either connector, not exceeding 70 N and a torque not exceeding 0,12 Nm to a limit of no more than 90°.

Rotate threaded connectors in a clockwise manner. Hold the maximum assembly force for no less than 10 s.

After 10 seconds of engagement, without activation of any latch or disengagement mechanism, an axial force of separation to the assembled connectors should be applied to a maximum 0,02 N (2 gf). Ensure the assembled connectors disengage.

If applicable, for threaded connectors, repeat the process above by assembling the connectors in a counter-clockwise manner. The process should be repeated for every potential assembly surface.

Microbiological integrity testing of prefilled neuraxial syringes

All intrathecal chemotherapy have to prepared in chemotherapy safety cabinets in hospital pharmacy departments. Neuraxial syringes with safer connectors filled with chemotherapy need are capped and then transported to clinical areas for the intrathecal dose to be administered.

It is essential that all manufacturers of neuraxial syringes provide a dedicated syringe cap for this purpose and test results of microbiological integrity testing of the capped syringes.

The NHS Pharmaceutical Quality Assurance Committee have produced a protocol for this test.[5]

Test results of these tests should be provided to healthcare purchasers.

Microbiological integrity test details

A batch or at least 20 syringes filled with sterile Tryptone Soya Broth (TSB) are sealed with the appropriate cap. These broth filled syringes are pre-incubated at 20-25C for 7 days, then 30-35C for 7 days to ensure that the aseptic fill has been carried out correctly and the contents are sterile. Any syringes showing turbidity or microbial growth are discarded.

Whole immersion test.

Inoculate a container(s) housing the syringes immersed in broth with 1 ml of the 18-24 hour culture of *Brevundimonas diminuta*. Incubate the containers for 14 days at 30-35C. Following incubation remove syringes from the broth culture and examine each syringe for tubidity/growth showing *Brevundimonas diminuta* access into the syringe. The integrity of the syringe/hub system is confirmed providing that the broth in all syringes remains free from growth.

Assessment of Non-Interchangeability with Standard Luer Connectors.

The aim of this test is to assess whether the non-Luer connectors can cross-connect with a selection of standard Luer connectors found on a comprehensive range of devices with Luer connectors found in clinical practice. Details of the products tested should be recorded. Multiple samples of each device are necessary to avoid the reuse of devices which may become deformed with multiple tests.

A panel of clinicians including anaesthetists, oncologists, pain specialists, pharmacists and intensivists should perform these tests under laboratory conditions. If the devices are intended for use in children, then paediatric specialists should also be asked to try to connect each of the Luer connectors to the candidate non-Luer connector. Each potential connection is graded as follows:

F Full - connectors fit together and lock mechanism appears to engage.

P Partial - connectors may fit together but locking mechanism cannot be activated or connectors will not stay connected under gravity.

N None - user was not able to connect the components together.

Each Full or Partial connection is further graded as male/female, male/male, or female/female.

Photographs of each Full or Partial connection are taken. Full or partial connections will then be further examined to assess whether they would allow passage of a 1ml bolus injection. The degree of leakage is recorded.

3. Clinical Simulation Testing

The recommended clinical simulation testing methods are based the on study methods used by Cooke et al and performed by the Department of Anaesthesia at the Royal United Hospital NHS Trust Bath with assistance from Bath Institute for Medical Engineering.[2]

Usability testing should be undertaken in four simulated clinical settings; spinal anaesthesia, epidural analgesia and anaesthesia, intrathecal chemotherapy, lumbar puncture using anatomically realistic spinal trainer manikin.

If the medical devices with the safer connectors are intended for paediatric use, simulations involving paediatric clinical settings are required.

Clinicians who perform neuraxial procedures in their routine practice, as part of their range of relevant skills and experience, should be recruited to participate in the simulation testing. These include anaesthetists, oncologists, paediatricians and physicians. All participation should be entirely voluntary. The study should in no way be an evaluation of the clinician's competence or performance.

3.1 Equipment

Central Neuraxial Equipment
Standard equipment for each clinical scenario:

Spinal Simulation
25G Whitacre spinal needles and 3.0ml (or 2.5ml) syringes with Luer-lok connectors

Epidural Simulation
16G (or 18G) Tuohy needles with loss of resistance syringes (Luer slip) and 10 ml injection syringe (Luer slip)
Epidural catheters, epidural filters and slip connector 10 ml syringes (if available)

Intrathecal Chemotherapy Simulation
22G Quincke and 22G Whitacre needles (if available) with introducer and 10ml syringes with Luer slip connectors.

Lumbar puncture
22G Quincke or Whitacre spinal needles and 5 ml slip syringe plus introducer and manometer.

The non-Luer connector neuraxial devices to be tested
Matching the above equipment.
Supplied by participating manufacturers: with essential training

3.2 Training

Training literature/demonstrations in the use of the devices under testing should be requested from the manufacturers and participants should be appropriately informed and trained before use. There should be no time restrictions on the period of training/familiarising; this should be as long as the participant wishes before they consider themselves familiar with the equipment and ready to perform the procedure.

To ensure independence of the testing procedure, manufacturer's representatives should not be allowed to attend the usability assessment sessions.

3.3 Simulation Protocol

Each clinician should perform the simulated procedure once for the standard equipment and then once for each alternative non-Luer connector device. If more than one non-Luer device is evaluated the order of these should be randomly determined by each participant, using a robust randomisation method. Video recordings of each participant are desirable wherever possible. Participants should be instructed to perform the procedure safely and in the time they would usually take.

The participants should also be offered the opportunity to determine whether the equipment under testing can 'cross-connect' with Luer devices.

3.3.1 Usability and performance

Data, relating to clinical acceptability and user satisfaction, should be collected via a structured interview that examines each component of the use of the new connectors, using a 5-point modified Likert scale and by video recording.
It is recommended that the following scale is used to asses usability and performance.

1 very difficult/very poor;
2 less than acceptable;
3 acceptable;
2 good;
3 very easy/very good)

relating to appearance, handling, ease of attaching syringe and needle, connection security, cerebrospinal fluid (CSF) visibility through the hub, ease of injecting and robustness of the equipment

In addition to the structured interview a few open- ended questions should be asked to allow identification of any issues or concerns related to the new devices. The overall usability score for each new system should be provided by each participant using a 10-point scale, with 0 being totally unacceptable and 10 being excellent. Data analysis should be based on interview responses and observations.

3.3.2 Cross connectivity

The participants should be offered the opportunity to determine whether the equipment to be tested can 'cross-connect' with Luer devices (either in combinations and conformations that are designed to occur or others) when used in a manner that might arise clinically. This may involve using the device in a manner that is outwith the manufacturer's instructions for use. However, participants should not be allowed to alter the equipment, or make connections which it is not reasonable to anticipate might be made by human error. A random selection of Luer equipment (available from the hospital's standard equipment) should be used (a list of the devices tested should form part of the test results, accepting that this is not an exhaustive test.

3.2.3 Sample size

It is recommended that simulation testing should be undertaken with a minimum of 10 anaesthetists and 5 oncologists/physicians.

Targets are
Spinal and epidural simulation: 10 each,
Lumbar puncture simulation: 10 each,
Intrathecal (oncology) injection: 10 each,.
Lumbar puncture; 10 each,
These are convenience samples.

3.2.4 Statistical analysis

Testing of devices should be performed using structured interview and assessments of aspects of performance based on the modified Likert scales. Statistical analysis using non-parametric testing is recommended to identify differences in performance. Wilcoxon sign rank test can be used to compare each device against the standard equipment performance.. Cross-connectivity issues do not require statistical analysis.

4. Where to send test result information

It is recommended that results of independent technical and usability test are sent to NHS Supply Chain, Welsh Healthcare Supplies, the NPSA (soon to be replaced by Patient Safety Sub-committee in the NHS Commissioning Board when the NPSA is discontinued as an organisation in 2011) as well as individual NHS organisations.

References

1) National Patient Safety Agency Patient Safety Alert. Safer spinal, epidural and regional anaesthesia devices – Parts A & B. November 2009. www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=65259
2) Cook T, Payne S, Skryabina E, Hurford D, Clow E, Georgiou A. Safer Neuraxial Connectors. A simulation based evaluation of two proposed alternatives to Luer devices for use in neuraxial anaesthesia. Anaesthesia 2010.65:1069-79.
3) Walker IA, Griffiths R and Wilson IH. Editorial. Replacing luer connectors: still work in progress. Anaesthesia 2010; 65:1059-1068
4) Donaldson L. Chief Medical Officer Annual Report 2002. London: Department of Health, 2003. www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_4006432
5) NHS Pharmaceutical Quality Assurance Committee. Microbiological protocol for the integrity testing of prefilled syringes. 1st Edition. February 2006. www.tset.org.uk/.../Micro%20Protocol%20%20integrity%20testing%20of%20syringes%20Publication%20version%20