Final report on usability study on 80369-6 connectors - revised

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Background: This document replaces 210N615. The document has been revised to correct an error on pg. 47, line 38. The previous version said 19% instead of 9%.
Usability study on ISO 80369-6 connectors (2014-12-31) - JWG4 N288
(replaces N285)

Summative usability testing of the ISO 80369-6 small-bore connector for use with ‘Neuraxial’ medical devices

Report Date: 25th November, 2014

Authors: Tony Wilkes¹, Philip Bickford Smith², Loretta Dorn³, Pete Phillips⁴

Summary
Fifty-five participants (38 clinicians and 17 nurses) in four different centres in the United Kingdom (Bridgend, Bath, Leicester and Bristol) took part in a usability study testing the new ISO 80369-6 small-bore connectors intended for use with medical devices for neuraxial procedures. The tasks that were tested in the study represent typical clinical work flows in most countries. Expert anaesthetists from other nations reviewed the protocol to ensure that all tasks tested considered a similar work flow as tested by the UK group. The usability testing is intended to demonstrate usability in all countries.

Procedures were carried out on manikins and included: spinal anaesthesia (P1); lumbar puncture and chemotherapy (P2); lumbar puncture, CSF collection and pressure measurement (P3); epidural catheter placement and bolus injection (P4); and an ICU / PACU setting (N1). All participants then carried out cross-connection tests attempting to connect male and female ISO 80369-6 lock connectors with various connectors on other medical devices.

All procedures were carried out successfully apart from

- lumbar puncture and chemotherapy procedure, where the three-way tap originally supplied for the study leaked at the connection between the tap and the needle hub (this three-way tap was replaced for the remainder of the study by a Neurax three-way tap)
- CSF collection and pressure measurement, where the manometers originally supplied for the study had non-rotating locking collars, which made them difficult to use (these manometers were replaced by Neurax manometers for the remainder of the study).

Whilst the intention was to use identical devices which only differed in the connector design, devices with Luer and non-Luer (ISO 80369-6) connectors had to be sourced from different manufacturers. The design of these variants was unavoidably different, even allowing for the different connectors. It was therefore not possible to blind the participants to the devices they were using. Furthermore, for some procedures, participants were familiar with the devices with Luer connectors (as they used them in their routine clinical practice), but were unfamiliar with the design of the devices supplied with non-Luer connectors provided for the same procedures.

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1 Independent medical device consultant, Hengoed, Wales, UK, and Study Coordinator for this project.
2 Consultant Anaesthetist (Retired), Bradford, UK
3 Associate Director Clinical Development at Baxter Healthcare, Chicago, Illinois, United States
4 Director, Surgical Materials Testing Laboratory, Princess of Wales Hospital, Coity Road, Bridgend, South Wales, CF31 1RQ, UK. T: +44-1656-752820. Correspondence to: P. Phillips: pete@smtl.co.uk
Although participants were given time for familiarisation, there was a potential risk of bias towards the more familiar equipment, which may have affected the overall scores, particularly for procedures P3 and P4, although none of the comments made by the participants related to the connector itself.

Apart from the instances described above, all connections were leak-free and all procedures were completed. All participants were asked whether they would be happy to use the connector in their current practice. In this case asking if they would be 'happy' was intended to mean they would be willing to use the new connectors in patient practice based on using them in a simulated environment. The numbers responding YES for each procedure were as follows:

- Intrathecal injection procedure P1 (21 participants): 21/21 (100%)
- Chemotherapy procedure P2 (9 participants): 7/8 (88%)
- CSF collection and pressure measurement P3 (15 participants): 14/15 (93%)
- Epidural procedure P4 (18 participants): 14/18 (78%)
- Nursing procedure N1 (17 participants): 17/17 (100%)

The users (55 participants) were asked to attempt connections between devices not intended to connect, to understand if a cross connection could be made. The users were asked to try to make the connection and some used significant force. Not all the new ISO 80369 series connectors were ready for the study therefore some of the connectors used for the cross connection study are the designs currently available and used in the market. Cross-connections were identified during the testing between:

- the male ISO 80369-6 connector and
  - the Luer slip injection port (i.e., the capped port on the top) of a peripheral ported IV cannula (39/55, 71%)
  - the female Luer connector on the following existing devices
    - IV cannula (5/55, 9%)
    - breathing system filter (currently on market) (7/55, 13%)
    - hypodermic needle (4/55, 7%)
  - ‘fir-tree’ nipple (ISO 13544-2) from a respiratory gas flow-meter (currently on market) (9/55, 16%)
  - balloon inflation port (Luer slip) of a Foley catheter (currently on market) (2/55, 4%)
- the female ISO 80369-6 connector and
  - the male protrusion of a screw-threaded NIBP cuff-inflation tubing connector (similar to that described in Appendix H of ISO 80369-5) (12/55, 22%)
  - female ISO 80369-3 (enteral) connector (7/55, 13%)

In the majority of cases, the connection was not functional, usually requiring significant force to achieve engagement, and usually leaking profusely. Most misconnections to Luer connectors required the user to initially oppose the connectors at an angle to the linear axis.

A number of cross-connections between the slip variant of ISO 80369-6 and the female lock Luer connectors were also identified. Whilst not formally part of the test protocol, these cross connections have also been examined in some detail and are currently under investigation.

Overall:
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(replaces N285)

- No significant usability issues were identified with compliant ISO 80369-6 connectors during the study;
- Most problems encountered during the study were, in the opinions of the study team, device-specific, not connector specific;
- Some cross connections were detected between ISO 80369-6 and ISO 80369-7 devices. Most of these are believed to have no clinical impact (for example, because they leak so badly), but some (mainly the ISO 80369-6 male slip to ISO 80369-7 female lock) are potentially significant, and are the subject of further investigation by the ISO teams. See Annex G for further detail.

Introduction
Numerous publications have reported severe harm and death when medical devices and their associated connecting tubing, were inadvertently connected to devices intended to deliver medication via a different route. The risk of a misconnection of this kind is increased when devices involved are fitted with the 'universal' Luer connector. Examples include the mistaken administration of medicines intrathecally (into the spinal canal) which are intended to be administered intravenously, and the unintended intravenous delivery of enteral feed.

The International Organization for Standardization (ISO) has developed the multi-part ISO 80369 standard, which includes specifications for a series of small-bore connectors designed to reduce the risk of making inadvertent misconnection between the various types of connectors. Each of the new connectors within this series is assigned a specified medical field of application. The connectors have been designed with the intention of ensuring that dissimilar ones are non-interconnectable, thus minimizing cross-connection risks.

ISO 80369-6 specifies connectors that are to be used for neuraxial and regional anaesthesia applications, including intrathecal injections, epidural infusions, nerve blocks and infusions into wound areas.

ISO 80369-6 connectors have been assessed for potential mis-connectability with all of the other ISO 80369 series of specified connectors (including Luer). This was accomplished through the use of a Computer Aided Design (CAD) dimensional analysis. However a user validation study was required to ensure that the proposed final design was sufficient to

1. meet the clinician’s needs (i.e., that it performs acceptably in terms of connectability, leakage, sample collection, threading of stylets); and
2. mitigate the risk of mis-connection with other small-bore connectors commonly found in the healthcare environment.

A test protocol was written by members of the ISO 80369-6 Task Force in Winter 2013/14 with guidance and assistance from AAMI, UK and US clinicians, and human factors experts from the FDA. The protocol was reviewed by a number of experienced clinicians in the US and UK before being adopted and published as ISO JWG4 document N204.

ISO 80369-6 is not yet published, and at the time of writing it is a DIS (draft international standard). For the purposes of simplicity, this report will refer to the proposed design as ISO 80369-6.
Methods

Pilot Study

A pilot study was carried out in the Multiprofessional Education Centre, Princess of Wales Hospital, Bridgend, UK, on 21, 22, 24 and 29 July, 2014.

Ten participants (three anaesthetists, one paediatric oncologist, one haematologist, one ex-theatre nurse from the ‘1000 Lives Campaign’, an operating department practitioner (ODP), a theatre nurse and two nurses from the Intensive Care Unit (ICU)) were recruited. One participant (an anaesthetist) carried out the usability testing twice, once at the beginning and once at the end of the pilot phase, to give a total of 11 complete sets of data.

Procedures 1 to 5 (see below) were carried out a total of 20 times. The number of times for each individual procedure is shown in Table 1. All participants carried out the cross-connection procedure (see below).

All the participants completed their part of the study within the designated one hour period, although the participants did not generally carry out testing using non-Luer equipment due to it being unavailable at that time. Even so, the proposed schedule of up to seven participants per day for the formal study appeared to be workable.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of times usability testing completed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Luer</td>
</tr>
<tr>
<td>P1 Spinal Anaesthetic</td>
<td>4</td>
</tr>
<tr>
<td>P2 Lumbar Puncture and Chemotherapy</td>
<td>2</td>
</tr>
<tr>
<td>P3 CSF Collection and Pressure Measurement</td>
<td>3</td>
</tr>
<tr>
<td>P4 Epidural catheter placement and bolus injection</td>
<td>4</td>
</tr>
<tr>
<td>N1 PACU / ICU</td>
<td>5</td>
</tr>
<tr>
<td>PN2 Cross-connections</td>
<td>11</td>
</tr>
</tbody>
</table>

Table 1: Number of times usability testing was completed in the pilot study.

Not all the equipment required for the testing had been supplied in time for the pilot study although some arrived during the pilot phase. In particular, equipment with the ISO 80369-6 connectors was significantly delayed, so most of the testing was carried out on Luer connectors only. Thus it was not possible to pilot procedures for pressure measurement (P3) and epidural procedure (P4) using non-Luer kit. This is reflected in the number of each procedure carried out.

Minor amendments were made to the protocol, including the data collection forms. These amendments were approved by AAMI through a series of briefing notes and telephone calls.

Main Study

Following completion of the pilot study, the main multi-centre study was carried out in the following four centres in the UK:

- Bridgend (Multiprofessional Education Centre, Princess of Wales Hospital)
- Bath (Department of Anaesthesia, Royal United Hospital)
The study was undertaken by the same people and the same manikins in each of the four centres to provide consistency. The study was carried out between 12 August and 23 September, 2014. Participants at each centre were generally recruited in advance. The protocol required a minimum of 30 doctors and 15 nurses overall. For the doctors, the aim was to have a clinical mix comprising participants from the following groups:

- Anaesthetists including both general and obstetric anaesthetists
- Oncologists/Haematologists, who regularly perform chemotherapy injection procedures
- General physicians/Neurologists for CSF pressure measurement
- Paediatric specialists from the groups above.

At least two participants from each of these groups was required by the protocol.

Nurses were recruited from Critical Care, Intensive Care and the Post Anaesthesia Care Units in the four centres. The lead at each centre was asked to invite clinicians and nurses with appropriate experience and covering these areas to participate.

Four procedures were offered to the clinicians and each clinician was asked to choose one or two simulated procedures to carry out for the study. The procedures were:

- Spinal anaesthesia (P1)
- Lumbar Puncture and Chemotherapy (P2)
- CSF Collection and Pressure Measurement (P3)
- Epidural catheter placement and bolus injection (P4)

All procedures were carried out using manikins. Procedures P1, P2 and P3 were carried out using a spinal injection simulator (Model AN1036, Adam Rouilly). Procedure P4 was carried out using a lumbar epidural injection trainer (Model APEIT100, Adam Rouilly). The manikins simulated adult patients. The intrathecal inserts were removed from the epidural manikins prior to the study to allow the epidural catheter to be inserted more easily.

All participants provided written informed consent on the understanding that the study was an assessment of the new connectors and not of their competence at carrying out the procedures. They were allowed an equipment familiarisation period before starting the study, including familiarisation with the manikin.

During the formal part of the study, video recordings of the participants carrying out the procedures were made using both a camera sited to one side of the participant and from video glasses worn by each participant. Each participant was asked to wear gloves whilst carrying out each procedure, but they were not required to wear or use any other particular items (e.g. gowns or goggles) unless they requested it.

During each procedure, the study moderator completed an observation form to assess the conduct of the procedure using a set of codes suggested by the FDA. Table 1 in document TC 210 JWG 4 N 204 provides definitions of passed, use error, close call, use difficulty, unresolved or not attempted. After each procedure, the participant was asked to complete a questionnaire. Each questionnaire comprised assessments of each part of the procedure marked on a five-point scale:

1. Unacceptable
2. Poor
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3. So-so
4. Good
5. Excellent

**Procedures P1-P4 – spinal/epidural procedures**
Each participant was asked to complete each procedure twice, once with equipment supplied with
Luer connectors and once with equipment supplied with the ISO 80369-6 connectors. The order of
the use of Luer and non-Luer equipment was randomly allocated. Block random allocation was used
as the aim was to have similar numbers of participants whose first assessment used Luer and non-
Luer equipment. Blocks of 10 participants were used for procedures P1 to P4 with further blocks of
10 generated as required (blocks with fewer participants were generated close to the end of the
study).

For procedures P1 to P4, the clinician was asked to draw up local anaesthetic for the skin and to
press the hypodermic needle of the syringe onto the skin of the manikin, but not inject the drug. As
the drawing up needle, syringe and hypodermic needle used for this part of the procedure had Luer
connectors, this introduced a mix of equipment into the trays, both Luer and non-Luer, providing an
opportunity for clinicians to use the wrong equipment for specific routes of administration for the
non-Luer procedures.

**Procedure N1 – ICU /PACU Nurse procedure**
The order in which the nurse undertook the procedures (IV or epidural connections first) was
managed through block random allocation. A block of 16 participants were used for procedure N1
with a further block of 2 participants generated as the number of nurse participants exceeded 16
(the original aim was to have at least 15 nurse participants).

A ‘fashion’ manikin (Songmics International) was arranged with an NIBP cuff, an oxygen face-mask
with oxygen tubing, an enteral feeding tube (Corpak) with ISO 80369-3 connectors, a peripheral IV
catheter with Octopus 2 Bionector (Vygon) attached, a single lumen central line in the chest wall, an
epidural line with filter with ISO 80369-6 connectors, and a Foley catheter with drainage bag.

In addition, IV, enteral and epidural infusion pumps were set up around the manikin, and the manikin
had a NIBP cuff on its arm with a floating connector.

Detailed instructions for all the procedures are to be found in Annex B.

**PN2 – Cross-connection procedure**
Each participant was then asked to carry out the cross-connection procedure which involved
attempting to connect male and female lock ISO 80369-6 connectors (which were attached to short
(~15 cm) lengths of tubing) to other devices using a variety of connectors found in the healthcare
environment. Devices with ISO 80369-2 and -5 connectors were not available for the study and so
were not included in the cross-connection procedure. The devices included were:

A. Peripheral IV catheter with side port (Luer) (Terumo)
B. Catheter Extension set (Luer) (Baxter)
C. Enteral feed connector (ISO 80369-3), male and female (Corpak)
D. Breathing system filter (Flexicare adult Venticaire\(^5\)) (Luer gas sampling port)

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5 Intersurgical Filta-Therm breathing system filters were used for the first nine participants whilst
waiting for delivery of the Flexicare filters.
E. Foley catheters (Porges silicone Tiemann tip catheter for most of the study, which was replaced by a Bard Foley latex catheter for the final few participants);

F. NIBP cuff inflation tubing fitted with 4 different connectors of configurations described in ISO 80369-5:
   a. B1-style male (Rectus);
   b. B2-style female (Rectus);
   c. B3-style male (CPC); and
   d. Appendix H-style male (Clippard Cinti-O)

G. ‘Fir-tree’ nipple from a respiratory gas flow-meter (East Healthcare)

H. 10 ml slip syringe (Luer) (BD Plastipak) and hypodermic lock needle (Luer) (BD)

I. epidural catheter filter (Smiths Medical) (ISO 80369-6)

The instructions given to each participant are detailed in Annex B. Each participant was given the following instructions:

1. “Attempt to connect each of the devices on the benchtop in front of you (working from left to right) to the non-Luer epidural connectors (male and female) attached to the short piece of tubing. Some of these connections are possible and others will be difficult or impossible.

2. After each connection, please inform the moderator how easy or difficult the connection was. The questions on the form are labelled with a letter from A to I which correspond to the labels on the table in front of you. The ease of connection is made on a five-point scale:
   - very difficult or impossible
   - difficult
   - so-so
   - easy
   - very easy

3. You can check whether a connection has been made by picking up the end of the tube opposite to that with the epidural connector - if the devices come apart under their own weight when held vertically, then the connection has not been made. If a connection has been made, you will be asked whether the force that you applied was force that you would be happy to use in clinical practice;

4. Move onto the next and subsequent connectors until all have been tested in this way and all questions answered”.

5. During the test, the study coordinator recorded answers and prompted participants to ensure they tested all necessary aspects of the connectors.

Debriefing session

Following the cross-connection procedure, each participant was asked to respond to further questions related to the use of connectors in their clinical practice, including whether they could imagine where the use of ISO 80369-6 connectors could go wrong and whether they currently use non-Luer neuraxial connectors in their clinical practice.

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6 If a connection was made which supported its own weight, this was further investigated by the study team for leakage, or passed onto one of the ISO sub-groups for investigation.
**Results**

**Participants**

Fifty-five participants were recruited, all of whom completed the study (Table 2).

<table>
<thead>
<tr>
<th>Centre</th>
<th>Doctors</th>
<th>Nurses</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bridgend</td>
<td>11</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>Bath</td>
<td>12</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>Leicester</td>
<td>8</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Bristol</td>
<td>7</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>38</td>
<td>17</td>
<td>55</td>
</tr>
</tbody>
</table>

Table 2: Numbers of participants recruited at each of the four centres.

The clinical mix of the 38 doctors is shown in Table 3.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetics</td>
<td>18</td>
</tr>
<tr>
<td>Anaesthetics and ICU</td>
<td>3</td>
</tr>
<tr>
<td>Neurology</td>
<td>2</td>
</tr>
<tr>
<td>Haematology</td>
<td>5</td>
</tr>
<tr>
<td>Oncology</td>
<td>4</td>
</tr>
<tr>
<td>Acute medicine</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>38</td>
</tr>
</tbody>
</table>

Table 3: The clinical mix of doctors recruited for the study.

Two of the anaesthetists, three of the oncologists and one haematologist specialised in paediatrics.

Seven of the anaesthetists specialised in obstetrics.

The procedures carried out by the participants are shown in Table 4. Twenty-six doctors carried out two procedures each and 12 doctors carried out one procedure. Procedures P1 to P4 were all carried out twice using both Luer and non-Luer devices. Therefore, the total number of procedures carried out was 200.

One participant’s data (Subject 4) was removed from the analyses as there was a misunderstanding regarding the appropriate experience required for P2, and S4 did not fully meet the criteria. Post-study video analyses by 2 senior experienced doctors supported this decision.
Table 4: Numbers of procedures carried out by the participants recruited at each of the four centres.

Note: results from one participant were subsequently removed from the analysis (see text for details).

Equipment issues – Changes & Substitutions

All equipment changes were discussed with the project team and authorised by Scott Colburn, Convener of ISO/TC 210-IEC/SC 62D/JWG4.

The issues discussed below are a consequence of trying to organise a study using devices which are not yet on the market as the standard is not finalised. Therefore each manufacturer who volunteered to provide samples for the study has had to come up with a way to produce a non-Luer ISO 80369-6 compliant version of their existing Luer design, and this has not been trivial. The discussion below is therefore not a criticism of the suppliers, but instead is intended to explain how the issues which arose were addressed in a manner intended to reduce the impact on study timelines.

Tuohy Needles

The Tuohy needles supplied did not have wings attached. Wings from NCC UK Ltd were sourced and were used with the non-Luer Tuohy needles, but the wings did not fit securely on the Luer Tuohy needles. Initial attempts to use these Tuohy needles with non-secure wings caused problems for the first two participants carrying out the epidural procedure, and so Luer Tuohy needles supplied by Smiths Medical US were used for the study. The wings on the two types of needle were therefore very different (Figure 1).
Figure 1: Tuohy needles. Luer (top); non-Luer (bottom).

Figure 2: Tuohy Needle - Luer
Tuohy Borst Adaptor (TBA)
The design of Tuohy-Borst adaptors supplied for use to connect the epidural catheter to the filters, were very different for the Luer and non-Luer arms of the study (Figure 4). The version supplied for use with Luer equipment was a clamp-style design commonly in use in the UK. The version supplied for use with non-Luer equipment was a push-fit design which participants had not used before.

Epidural Catheter
Both the epidural catheters supplied for the study were more flexible than those commonly used in the UK. The catheters were supplied from two different manufacturers and had different designs. In addition, neither catheter had a ‘window’ to view the meniscus of liquid within the catheter.
3-Way Taps & Manometers

The Intervene 3-way taps (and taps with manometers) supplied for the study had fixed locking collars (non-rotating). In addition, the manometer was bonded into the tap. This meant that during the P3 study, the 3-way tap and manometer had to be rotated to make a secure connection with the spinal needle, which entailed rotating a 20cm or longer piece of rigid plastic tubing around the axis of the spinal needle. This was not clinically acceptable due to the risk of dislodging the needle tip from the intrathecal space, and participants were not happy to use these devices in the study.

Furthermore, the 3-way tap leaked at the junction between the 3-way tap and the needle hub with the first 2 participants in the P2 study. Neurax on/off taps and Neurax manometers with a bonded 3-way tap were subsequently used in the non-Luer arms of the study for procedures P2 (Lumbar Puncture and Chemotherapy) and P3 (CSF Collection and Pressure Measurement), respectively.

It is important to note that the Neurax (non-Luer) manometer and the manometer used in the Luer arm of the study (both supplied by Rocket Medical) are very different, due to the fact that the Neurax devices are Luer devices with non-Luer adaptors bonded onto the arms (Figures 6 and 7).
Thus in comparison, the length of the 3-way tap on the Luer manometer is much shorter and there is a slip connection on the arm which engages with the needle hub. The arms on the non-Luer manometer are longer and have a rotating locking collar. The non-Luer manometer was also much longer than the Luer manometer (both were supplied in two sections); the non-Luer manometer was marked up to 57 cm, the Luer to 40 cm. Therefore, participants found it more difficult to keep the non-Luer manometer stable whilst it was connected to the spinal needle in the manikin. This difficulty was then compounded as the collar on the connector had to be rotated to make a secure connection. A further minor comment was that the graduation markings on the non-Luer manometer were on the side, and so were difficult to read when the participant was sitting in line with the manometer and the manikin.

**Spinal Needles**

25G spinal needles were requested and supplied for the spinal anaesthesia procedure (P1). The design of the hubs on the Luer and non-Luer needles was slightly different (Figure 8). Despite the use of an introducer, needles bent when used by four of the 21 participants in the Luer arm of the study and by two participants in the ISO 80369-6 arm of the study during placement in the manikin. For the latter, the introducer needle bent for one of the participants. Clinicians commented on the stiffness of the ‘tissue planes’ in the manikins’, noting that they required more force to insert the needles, and it is thought that this may have contributed to the needle bending which occurred. It is not thought that the connector design contributed to this. In retrospect a slightly thicker needle (such as a 24G) may have minimised the risk of needles bending.
22G spinal needles were supplied for procedures P2 and P3. The Luer needle bent for one participant during placement in the manikin for procedure P3.

**Manikin Issues**

The manikins used for the study were specifically designed for use for training spinal anaesthesia and epidural analgesia procedures. However, some participants found it difficult to place the needles correctly in the manikins as the ‘feel’ of the tissues is quite different to patients. Some participants also found it difficult to thread the epidural catheter through the needle into the epidural trainer, although this was partly because the epidural catheters were very flexible.

**Equipment Familiarity**

Participants were generally familiar with the generic types of devices used but not necessarily the specific designs of each device. For the most part, participants were not observed to have problems with such equipment. The design of some devices, however, differed considerably from that in routine use in the UK, and this was especially the case for devices supplied with non-Luer connectors for procedures P3 and P4 (epidural catheters and manometers in particular), and this unfamiliarity may have had an impact on the results from those procedures.

**Results from the Procedures**

All the following graphs use the letters 'L' for Luer (ISO 80369-7) and 'NL' for non-Luer (ISO 80369-6).

The lower bar graphs show the difference in time (or attempts) between the Luer and Non-Luer procedures. If the Non-Luer (NL) procedure took longer, or required more attempts, then the difference is positive and the bar rises above zero. If the Non-Luer procedure was shorter or required fewer attempts, then the bar drops below zero.

**P1 Spinal anaesthesia**

Participants were offered both slip and lock versions of both Luer and non-Luer syringes for this procedure. Four of the 21 participants used slip syringes, the remainder (17) used lock syringes. All four of the participants preferring to use slip syringes were obstetric anaesthetists.
The time taken to complete the procedure was assessed using video footage. The results are shown in Figure 9.

*Figure 9 P1 – Total procedure time (L=Luer, NL=non-Luer)*
The time taken to find the intrathecal space and give the bolus injection was analysed from the video. Results are shown in Figure 10.
The number of attempts to locate the intrathecal space was recorded (see discussion of glitches in Annex E) and the results shown in Figure 11. A small number of clinicians required more than one attempt to locate the space. In general, participants observed that they found the manikin more difficult than a human, and it is believed that this may have contributed to the number of repeat attempts.

Figure 11: P1: Number of attempts required to locate the intrathecal space.
Each procedure was observed for leaks, and the severity of leak classed as None (0), Moderate (+) or Excess (++)

The results are summarised in Figure 12.

![Figure 12 P1: Leakage during bolus injection](image-url)
After the procedure, all participants were asked a series of questions regarding the performance of both connector variants:

- Q1 Connecting the syringe/3-way tap to the spinal needle
- Q2 Ability to keep spinal needle immobile whilst connecting the syringe/3-way tap to the spinal needle
- Q3 Security of the connection between the syringe or 3-way tap and needle
- Q4 Ability to re-insert the needle stylet
- Q5 Ability to observe CSF at the hub
- Q6 Ease of CSF collection without compromising the sample quality (Only answer if CSF collection undertaken) (not used for procedure P1)
- Q7 Ability to disconnect the syringe/3-way tap from the spinal needle without moving the spinal needle
- Q8 Hand hold comfort
- Q9 Effect on technique used to hold and anchor the device.
- Q10 Intuitiveness of use of the connectors
- Q11 Leakage of fluid from connectors during the procedure.
- Q12 Effect on usual technique & workflow

The responses to these questions are summarised in Figure 13.

Figure 13: Questionnaire results from P1

The scale used goes from 1 (Unacceptable), through to 5 (Excellent). See Page 5 for further details.
All users were asked if they would be happy to use devices fitted with this connector in their normal clinical practice. These responses are summarised in Figure 14.

Figure 14: "I would be happy to use devices fitted with this connector in my normal practice."

Summary of P1

- All 21 participants were happy to use devices fitted with either Luer or ISO 80369-6 connectors;
- No leaks were recorded during P1 with either Luer or ISO 80369-6 connectors;
- Four of the Luer needles bent during P1;
- Two of the non-Luer needles bent during P1;
- 5 Luer and 3 non-Luer users required more than one attempt to locate the intrathecal space;
- One user scored handheld comfort of NL as poor. This is thought to be device-specific, not connector related;
- Two users recorded the ease of stylet reinsertion of NL as poor;
- Two users scored the effect of the NL device on their usual workflow as poor. In both cases, the comments related to the difficulty in drawing up the ‘drug’; hence, this was probably related to the narrower bore of the non-Luer drawing up needle restricting flow (see Annex D for comments on this).
**P2 Lumbar Puncture and Chemotherapy**

The total procedure times taken from the video footage are summarised in Figure 15.

*Figure 15: P2- Total procedure time*
The time taken to connect the syringe to the 2/3-way tap and deliver the two chemotherapy bolus injections was timed using video footage and summarised in Figure 16.
The time taken to attach the 2/3 way tap to the spinal needle was recorded and summarised in Figure 17.

*Figure 17: P2 - Time taken to attach the 2/3 way tap to the spinal needle.*
Each chemotherapy injection was observed for leaks, and the severity of leak classed as None (0), Moderate (+) or Excess (++)

**Figure 18: P2 - Leakage of chemotherapy drugs during injection**

**NOTE:** Subject 7 did not attempt to inject the second syringe of chemotherapy in the NL arm due to the leak experienced with the first syringe. This explains the missing data in the NL arm.
After the procedure, all participants were asked a series of questions regarding the performance of both connector variants:

Q1  Connecting the syringe/3-way tap to the spinal needle
Q2  Ability to keep spinal needle immobile whilst connecting the syringe/3-way tap to the spinal needle
Q3  Security of the connection between the syringe or 3-way tap and needle
Q4  Ability to re-insert the needle stylet
Q5  Ability to observe CSF at the hub
Q6  Ease of CSF collection without compromising the sample quality (Only answer if CSF collection undertaken) *(not used for procedure P1)*
Q7  Ability to disconnect the syringe/3-way tap from the spinal needle without moving the spinal needle
Q8  Hand hold comfort
Q9  Effect on technique used to hold and anchor the device.
Q10 Intuitiveness of use of the connectors
Q11 Leakage of fluid from connectors during the procedure.
Q12 Effect on usual technique & workflow

The responses to these questions are summarised in Figure 19.

The scale used goes from 1 (Unacceptable), through to 5 (Excellent). See Page 5 for further details.
All users were asked if they would be happy to use devices fitted with this connector in their normal clinical practice. These responses are summarised in Figure 20.

**Summary of P2**

- Results from one of the nine participants were removed from the study as the participant was less experienced than required in the protocol;
- Seven of the remaining eight participants were happy to use devices fitted with the Luer connector. The remaining participant is a user of the Surety system (a proprietary non-Luer system), and therefore would not wish to return to a Luer-connector based system having already made the change to mitigate the risk of wrong-route injections.
- For the ISO 80369-6 devices, the first two participants (subjects 4 + 7) used Intervene equipment which included a 3-way tap that leaked at the connection between the tap and the needle hub. Both of these participants were not happy to use devices fitted with the ISO 80369-6 connector. One of these participants has been removed from the P2 study data as their experience did not meet the study criteria, however they are noted here because their experience helped identify the problematic connector.
- Six of the remaining seven participants used a different make of tap (Neurax): this device did not leak at the junction between the tap and the needle hub. The one remaining participant specifically chose not to use a tap. All seven participants were happy to use devices fitted with these connectors. One sample of the Neurax tap did leak at the junction where the non-Luer connector adaptor had been bonded onto the tap. This was not a connector-related issue, but rather an assembly issue – the connection itself did not leak – and so was not scored as a leak in the above analyses.

- In the questionnaire (Figure 19), the scores of Poor or Unacceptable were given by Subject 7 who experienced leaks with the Intervene 3-way tap before it was substituted.

SMTL and Smiths USA have performed liquid leak testing on the Intervene 3-way taps. SMTL tested 2 samples and found both samples leaked. Smiths tested 10, where 2/10 were found to leak. Further work is required to understand whether the Intervene 3-way taps leaked due to being out of dimensional specification, material issues, or surface characteristics.

The lower scores in Figure 19 generally reflect the devices used initially, before the switch to using the Neurax devices. This can be seen in Figure 21 below, where the data from Figure 19 has been re-analysed without the Intervene device.

Figure 21: Questionnaire results from P2 (without Intervene devices)
P3 CSF Collection and Pressure Measurement

The time taken to complete the procedure was assessed using video footage. The results are shown in Figure 22.

Figure 22: P3: Total procedure time
During P3, participants were asked to collect a CSF sample, after inserting the spinal needle but before measuring the pressure. This video footage was analysed to ascertain whether there was any fluid creep around the needle onto the non-fluid pathway (drop creep). The results are shown in Figure 23.

Figure 23: P3: Drop creep during CSF collection.
The time taken to find the intrathecal space and collect the CSF was timed. The results are shown in Figure 24.

**Figure 24: P3: Time taken to find the intrathecal space and collect the CSF sample**
The time taken to attach the 3-way tap and measure the intrathecal pressure was timed and is displayed in Figure 25.

*Figure 25: P3: Time taken to attach 3-way tap to the spinal needle and measure the intrathecal pressure.*
The connection between the 3-way tap and the manometer were observed for fluid leakage during the procedure. Leaks were classed as None (0), Moderate (+) and Excess (++)

![Bar chart showing leakage during diagnostic lumbar puncture (DLP)](image)

*Figure 26: P3: Leakage during diagnostic lumbar puncture (DLP)*
After the procedure, all participants were asked a series of questions regarding the performance of both connector variants:

Q1 Connecting the syringe/3-way tap to the spinal needle
Q2 Ability to keep spinal needle immobile whilst connecting the syringe/3-way tap to the spinal needle
Q3 Security of the connection between the syringe or 3-way tap and needle
Q4 Ability to re-insert the needle stylet
Q5 Ability to observe CSF at the hub
Q6 Ease of CSF collection without compromising the sample quality (Only answer if CSF collection undertaken) (not used for procedure P1)
Q7 Ability to disconnect the syringe/3-way tap from the spinal needle without moving the spinal needle
Q8 Hand hold comfort
Q9 Effect on technique used to hold and anchor the device.
Q10 Intuitiveness of use of the connectors
Q11 Leakage of fluid from connectors during the procedure.
Q12 Effect on usual technique & workflow

The responses to these questions are summarised in Figure 27.

The scale used goes from 1 (Unacceptable), through to 5 (Excellent). See Page 5 for further details.
All users were asked if they would be happy to use devices fitted with this connector in their normal clinical practice. These responses are summarised in Figure 28.

Summary of P3

- Fourteen of the 15 participants were happy to use devices fitted with the Luer connector. The remaining participant is a user of the Surety system (a proprietary non-Luer system), and therefore would not wish to return to a Luer-connector based system having already made the change to mitigate the risk of wrong-route injections.

- Fourteen of the 15 participants were happy to use devices fitted with the ISO 80369-6 connector. The remaining participant was not happy to use the new connector as the male 80369-6 connector used to connect the 3-way tap/manometer assembly to the spinal needle hub had a locking collar; the 3-way tap on the manometer used in the Luer arm of the study had a slip connector which the participant found much easier to use. The participant was informed that production products could have either slip or lock collars, and that this was a choice for manufacturers, and not dictated by the standard. Therefore, this was a device-related rather than connector-related issue (confirmed via subsequent e-mails with the participant).

- Participants took longer to connect the non-Luer 3-way tap to the spinal needle and measure the intrathecal pressure as the pre-assembled tap/manometer plus the use of Luer/non-Luer adaptors in the tap made the device heavier and more cumbersome, and the video footage
shows users struggling to balance the assembly and make the connection. If devices
compatible with current practice had been available, we suspect that such differences would
not have been observed.

- It should also be noted that the users were asked to measure the CSF pressure to their
  satisfaction, which resulted in differences between the two device variants. Some of these
  may be explained by the connector design and some which may be explained by the device
  itself.

- It should also be noted that the Luer tap was of a slip design, whereas the non-Luer device
  had an ISO 80369-6 lock connector.

- The poor scores for the Luer devices were generally related to the slip connector on the two-
  way tap; participants sometimes found it difficult to maintain a secure connection. The
difference between the action of the levers on the two taps (Luer and non-Luer) was also
commented on.

- For non-Luer devices, the poor scores were generally related to the use of adaptors which
  made them cumbersome and more difficult to maintain in the correct orientation. T

- Rotating the locking collar on the three-way tap required careful handling and positioning of
  the participant's fingers; those unfamiliar with this technique tended to score this aspect
  low.

- One participant used a 25G needle with an introducer rather than the 22G spinal needle as
  that reflected their usual practice.
P4 Epidural catheter placement and bolus injection

The time taken to complete the procedure was assessed using video footage. The results are shown in Figure 29.

Figure 29: P4 - Total procedure time
The time taken to connect the filter to the catheter adaptor, and to connect and disconnect the administration line to the filter was measured and is shown in Figure 30. Note that some users assembled the adaptor and filter during tray preparation, so it was not possible to analyse their time for this first step. These users are identified as “1” (circles) under “Subject Procedure”. Where “Subject Procedure” = 2 (triangles), these users connected the filter to the adaptor after placing the catheter (subjects 5 [L only], 9 [NL only], 11, 12, 33 [NL only] and 39).

Notes
1. Subject 24 had a problem with the connection between the administration set and the filter sticking, which accounts for the longer time taken for this procedure in the Luer arm.

2. Subject 9 forgot to use a filter for the Luer element and this was not picked up until post study. This data is therefore missing from the delta graph.
3. Subject 26 partially abandoned the Luer procedure due their irritation with the catheter, and
did not connect the administration line. This data is therefore missing from the delta graph.
The connections between the filter, adaptor, and catheter were observed for fluid leakage during the procedure. Leaks were classed as None (0), Moderate (+) and Excess (++). The results are shown in Figure 31.

Note that Subject 3 did not undertake the bolus injection for the Luer arm of the study, hence the discrepancy between the Luer and non-Luer data in Figure 31.

Figure 31: P4: Leakage during bolus injection
After the procedure, all participants were asked a series of questions regarding the performance of both connector variants:

- Q1 Connecting the loss of resistance (LOR) syringe to the epidural needle
- Q2 Threading the epidural catheter through the needle
- Q3 Connecting the catheter to the adaptor and filter
- Q4 Perception of the security of the connection between the filter and the catheter
- Q5 Ability to re-insert the needle stylet (deleted from questionnaire during study, participants were not asked to do this)
- Q6 Connecting the administration set to the filter
- Q7 Disconnecting the administration set from the filter
- Q8 Hand hold comfort
- Q9 Effect on technique used to hold and anchor the device.
- Q10 Intuitiveness of use of the connectors
- Q11 Leakage of fluid from connectors during the procedure.
- Q12 Effect on usual technique & workflow

The responses to these questions are summarised in Figure 32.

The scale used goes from 1 (Unacceptable), through to 5 (Excellent). See Page 5 for further details.
All users were asked if they would be happy to use devices fitted with this connector in their normal clinical practice. These responses are summarised in Figure 33.

**Summary of P4**

- Seventeen of the nineteen participants were happy to use devices fitted with the Luer connector; one of the remaining two participants was not happy to use the devices because the participant found it difficult to use the epidural catheter, which is therefore unrelated to the connector, and the other participant was generally unhappy with the equipment that had been supplied for the study (this participant was also unhappy to use devices fitted with the non-Luer connector).

- Fourteen participants were happy to use devices fitted with the ISO 80369-6 connector; four were not happy, but again this was related to the equipment (e.g. the catheter) rather than the connector itself; and one was unwilling to give an opinion (classed as NS – Not Stated – in Figure 33) without further experience of the new connector.
• However, in all cases, the procedures were completed successfully except for the Luer arm of the procedure with Subject 26 (see above).

• Luer and non-Luer devices were supplied by different manufacturers. Participants were generally more familiar with the devices from one manufacturer (supplied for the Luer arm of the study) and some experienced difficulty with using the less familiar devices supplied for the non-Luer arm of the study; some of the scores reflected this difficulty.

• Some devices intended for use in both the Luer and non-Luer arms of the study, particularly the catheters, were very different to those in typical UK clinical practice (e.g. much more flexible, no ‘window’ to see the meniscus, more stretchy when removing from the manikin). Some participants provided low scores because of these device specific characteristics.
N1 Nurse ICU / PACU

In Nursing procedure N1, each main element of the procedure was timed. The results are shown in Figure 34. Note that this study is different to the previous studies (P1 – P4), in that 3 devices connectors (Luer IV, ISO 80369-3 enteral, and ISO 80369-6 Epidural) were used in a single procedure.

Figure 34: N1: Total time per sub-procedure
During the Nursing procedure N1, each connection was studied for leakage during the bolus injection. Leaks were classed as None (0), Moderate (+) and Excess (++). The results are shown in Figure 35.

*Figure 35: N1: leakage during bolus injection for the three administration routes*
After the procedure, all participants were asked a series of questions regarding the performance of the different connectors.

Q1 - Connection of the Syringe to the peripheral IV catheter
Q2 - Connection of the IV administration set to the peripheral IV catheter
Q3 - Security of the IV administration set to the peripheral IV catheter
Q4 - Connection of the epidural syringe to the epidural catheter
Q5 - Connection of the epidural infusion tubing to the epidural catheter
Q6 - Security of the epidural syringe to the epidural catheter
Q7 - Connection of the enteral flush syringe to the feeding tube catheter
Q8 - Connection of the enteral administration set to the enteral feeding catheter
Q9 - Security of the enteral administration set to the enteral feeding catheter

The results are shown in Figure 36.

The scale used goes from 1 (Unacceptable), through to 5 (Excellent). See Page 5 for further details.
All users were asked if they would be happy to use devices fitted with this connector in their normal clinical practice. These responses are summarised in Figure 37.

**Figure 37**: N1: "I would be happy to use devices fitted with this connector in my normal practice."

**Summary of N1**

- Seventeen participants completed this procedure.
- All were completed successfully and there were no reported issues.
- In particular, no leakage occurred during the procedures.
- All participants were happy to use devices fitted with the ISO 80369-6 connector.
PN2 Cross-connection study

All 55 participants recruited for the study completed the cross-connection part of the study.

Cross-connections were identified between either male or female ISO 80369-6 connectors and the following components:

ISO 80369-6 female connector and ISO 80369-3 female (enteral)
This connection, between an enteral administration set to an epidural filter, was made by 7 (13%) of the participants, 6 of these rating the connection as 'easy'.

Comment
1. This cross-connection had been pre-identified by the ISO Task Force CAD team.
2. The force required to make the connection was measured in the laboratory (by SMTL and Smiths USA) and was recorded at between 65N to 69N. This is below the maximum limit from the ISO DIS 80369 cross connection test of 70N.
3. Bill O’Neil (Smiths USA) performed leak testing as identified in Annex H.5 of ISO/DIS 80369-6 (ISO/TC 210/JWG 4 N260) between these connectors and identified greater than 75% leakage when tested with water.
4. In practice, the fluid in the administration set would be a viscous feed, and it is considered that the small bore lumen used in epidural catheters and spinal needles would make it extremely difficult to allow any feed to pass spinally or epidurally.

ISO 80369-6 male connector and a peripheral IV cannula injection (side) port (ie. not the main Luer-lock port)
This connection was made by 39 (71%) participants, with 15 rating the connection as easy (12) or very easy (3); the remaining 24 participants who made the connection rated it ‘difficult’ (9) or ‘so-so’ (15).

Comment
1. The injection port is designed to enable needle-free injection into the cannula, and includes a valve mechanism at the bottom of the port. We suspect that this injection port is not compliant with ISO/DIS 80369-7 although this is still to be determined.
2. When attempting to inject water through the port, no fluid could be injected into the cannula. Thus the connection was non-functional.

ISO 80369-6 male connector to a female Luer connector
Three devices supplied for the cross-connection study (breathing system filter, Luer hypodermic needle and peripheral IV cannula (main port)) incorporated a female Luer lock connector. Some of the participants were able to connect the ISO 80369-6 male connector to the female Luer lock connector on these devices. Seven connections (13%) were made to the breathing system filter, 4 (7%) to the Luer hypodermic needle and 5 (9%) to the peripheral IV cannula. Ten of these 16
connections were rated as ‘difficult’; the remaining six were rated as either ‘so-so’ (1), ‘easy’ (4) or ‘very easy’ (1).

Comment

1. This connection was achieved in every case by twisting the ISO 80369-6 male connector onto the lugs on the Luer female connector at an angle to the linear axis. The connections that were made were secure (in that they supported the weight of the devices), but the
connection was clearly incorrect as the two devices remained at an angle to each other. Note that the test specified in the Annex of ISO 80369-1 for cross connection uses a straight, not angled, axial engagement mechanism.

2. Further work is required to assess the likelihood of leakage with these connections. Our suspicion is that most will leak substantially, but this will be confirmed during the CAD validation study presently underway with ISO.

3. Furthermore, the female Luer lock connectors were deformed during the cross-connection (Figures 40 and 41) so that subsequent cross-connection attempts were easier.

ISO 80369-6 male connector and the stepped fir-tree/Christmas-tree connector from an oxygen flow valve

A cross connection was made by 9/55 (16%) participants between the stepped fir-tree/Christmas-tree connector from an oxygen flow control valve and a male ISO 80369-6 connector.

Comment

1. The dimensions of the 'fir-tree' nipple specified in EN 13544-2 are incomplete: the internal diameter of the bore of the nipple is defined as equal to or less than 3.5mm.

2. This connector could potentially be replaced by the ISO 80369-2 connector (although CEN/TC215 has taken a decision to keep this connector for 'machine-end use').

3. In practice, this particular connector would usually be found at the respiratory gas outlet on the wall or on the top of a compressed gas cylinder. The possibility of connecting an ISO

Note that the "CAD validation study" is a systematic cross connection study of devices, designed to assess the reliability of the CAD model. This will be published by ISO in the near future.
80369-6 syringe or administration set to these outlets is considered to be remote and therefore not pose a significant clinical risk.

4. An alternative design of a fir-tree connector includes a fire-break in the fir-tree connector (see blue insert inside the lumen in Figure 42). This fire-break prevented a ISO 80369-6 male connector from making a secure connection.

ISO 80369-6 female connector and the nipple on a connector on a NIBP cuff inflation tube

Four such connectors for use with NIBP cuff inflation tubes of different design were supplied for the study: the cross-connection is only to one (see Figures 43 and 44) of the four connectors, which is a proprietary design and does not comply with ISO 80369-5. Eight (35%) of the participants made this cross-connection, but only one rated it as ‘easy’.

Comment

1. The nipple effectively blocks the fluid pathway, therefore no fluid can pass between the devices.

2. Whilst having a screw thread, the connector shown differs from the configuration described in the ISO 80369-5 Annex H, in that the nozzle projects beyond the front of the collar. The design set out in Annex H has no such projection. If correctly configured, no connection with the -6 female would have been achieved.

ISO 80369-6 male connector and the Luer inflation lumen of the Foley catheter

Two participants (4%) connected an ISO 80369-6 male connector to the Luer inflation lumen of the Foley catheter and rated this connection as either ‘difficult’ or ‘easy’. UsabilityStudy-ISO-80369-P47.pdf

Comment
1. This connector has a valve, which would not be opened when the ISO 80369-6 male connector is inserted. The clinical implications of this cross-connection are being investigated.

**All other cross connection attempts.**

1. No other cross-connections were made by the participants with any of the other devices.

2. Furthermore, all 55 participants rated the connections between the ISO 80369-6 male lock connector and the epidural catheter filter as either 'easy' (2) or 'very easy' (53), and between the ISO 80369-6 female connector and the epidural catheter filter as 'so-so' (1), 'easy' (7) or 'very easy' (47).

The scores from the assessments are shown in Table 5.

One participant suggested trying to cross-connect a slip syringe with an ISO 80369-6 male connector with connectors on the other devices used in the cross-connection test. This was not included in the original protocol. The results of this separate study are described in Annex G.

**Statistics**

The authors considered whether it was appropriate to present any statistical analyses in this report. After discussion with various study advisors, the conclusion was that a paper for a scientific journal would be the best way to present such analyses.

**Lessons Learnt**

- Where the equipment supplied was generally clinically-acceptable, for example for the spinal anaesthesia and nursing procedures, all the participants recruited for the study were happy to use devices fitted with the new connectors.

- Where participants were not happy to use the new connectors this was usually, on discussion with the participant, due to general equipment configuration and/or manikin issues, rather than being connector-related.

- Some cross-connections were identified with connectors on other devices. In the majority of cases, the cross-connection was not functional, usually requiring significant force, and usually leaked profusely. Most cross-connections with Luer connectors required the connectors to be introduced to each other at an angle. The test method specified in the standard is to oppose the two connectors with their respective axes in alignment.

- We were not able to try out the majority of the equipment supplied prior to the start of the formal part of the study. This would have been useful, in order to identify issues e.g. with the kit supplied for pressure manometry and epidural analgesia. As a result we had to make some equipment changes during the study.

- We should have included ISO 80369-6 ‘slip’ syringes in the cross-connection tests. Our reasoning for not doing so was because we thought the highest risk was from bupivacaine infusions, not bolus injection. If repeating this work, we would recommend inclusion of slip syringes alongside the lock variants, as the lack of threads in the collar (on both Luer and non-Luer devices) increases the risk of cross-connection.

- We requested either 24G or 25G spinal needles for procedure P1 (spinal anaesthesia); 25G needles were supplied. In retrospect, we should have requested 24G needles as the 25G needles tended to bend when used with the stiffer materials of the manikins.
Suggestions for Future Research

It would be useful to know more about the potential cross-connections between the male slip syringe variant of ISO 80369-6 and other devices, in particular female Luer lock connectors, as well as the significance of the clinical risk from such connections.

The study detected measurable differences in clinician performance between familiar and unfamiliar devices. This methodology could be used to investigate the impact of device design on these measures.

The authors, in conjunction with the study leads and advisors, intend to submit an analyses of this study to a scientific journal.

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- Professor Harold Thimbleby, Professor of Computer Science, specialising in Human Factors, Swansea University, UK;
- Dr Cathy Morley-Jacob, Consultant paediatric haematologist, Cardiff and Vale University Health Board, UK;
- Dr Rachel Collis, Consultant Obstetric Anaesthetist, Cardiff and Vale Health Board, UK.
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- BD: funding;
- Corpak: devices;
- Covidien: devices;
- Hunter International and NCC UK Ltd: Neurax devices
- Intervene: devices;
- Kimberley Clark: funding;
- Medline: funding;
- Pajunk: devices/components;
- Teleflex: funding;
- Smiths Medical: funding and devices;
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Declaration of Interests

This study was funded by industry through AAMI. None of the individual companies had any influence in the protocol nor the study as individual companies, only through the various working groups and task forces under ISO.

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The authors of the protocol and the report make the following declarations of interest:

- Dr Tony Wilkes: None
- Dr Philip Bickford-Smith: Co-inventor of the ‘Neurax’ connector system, which ceased to be marketed in 2012.
- Loretta Dorne: Employee of Baxter Healthcare
- Pete Phillips: Manages a UK NHS laboratory, SMTL, which undertakes commercial work for industry. SMTL has historically undertaken work for some of the funding partners, usually in unrelated fields, but no such work has been undertaken in the last 12 months.

AAMI funding was used to pay for the time of the study authors, study participants backfill time, lead clinician expertise, technicians, equipment, and travel/accommodation.

All participants in the study represented their own opinion, and not the opinion of any commercial entity, organisation, or vested interest.
### Table 5: Cross Connection Testing Results

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<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
<th>Cross connections</th>
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Annex A - First Article Inspection (FAI) of supplied devices

See attached document.
Instructions to Participants

The instructions given to the participants for each procedure were as follows:

**Spinal anaesthesia (P1)**

1. Draw up a volume of 3.0ml of spinal local anaesthetic, and add a further smaller dose of spinal opioid (using two syringes and filter needles) to simulate mixing of medication (such as a local anaesthetic and an opiate);
2. Prepare the syringe and needle you would use to give the local anaesthetic into the skin, but do not actually inject into the manikin;
3. Undertake the spinal injection as per your normal practice. Please fully withdraw and reinsert the stylet at least once during the procedure;
4. Finally, withdraw the spinal needle.

**Lumbar Puncture and Chemotherapy (P2)**

1. Prepare the syringe and needle you would use to give the local anaesthetic into the skin, but do not actually inject into the manikin;
2. Locate the intrathecal space with the spinal needle as you would normally, and take a sample of CSF. Please withdraw and reinsert the stylet at least once during the procedure;
3. If you would usually use a 2 or 3-way tap, attach that, and give the intrathecal injections (two pre-filled syringes labelled ‘IT Chemotherapy 1’ and ‘IT Chemotherapy 2’ will be provided and should be used to demonstrate syringe-swap with the spinal needle remaining in situ);
4. Finally, withdraw the spinal needle.

**CSF Collection and Pressure Measurement (P3)**

1. Prepare the syringe and needle you would use to give the local anaesthetic into the skin, but do not actually inject into the manikin;
2. Locate the spinal canal with the spinal needle as you would normally. Please withdraw and reinsert the stylet at least once during the procedure;
3. Using the supplied universal container, collect 5 drops of CSF;
4. Next measure the fluid pressure using the equipment supplied. You do not need to record the intrathecal pressure, however you should take sufficient time to ensure that the fluid column in the manometer has risen sufficiently that you could take a reading when it has stabilized. Collect the liquid from the manometer in the universal container;
5. Finally, withdraw the spinal needle.

**Epidural catheter placement and bolus injection (P4)**

1. Prepare the syringe and needle you would use to give the local anaesthetic into the skin, but do not actually inject into the manikin;
2. Draw up 7ml of saline into the loss of resistance (LOR) syringe;
3. Check the patency of the epidural catheter;
4. Locate the epidural space with the Tuohy needle and LOR syringe as you would normally;
5. Insert the epidural catheter, as you would normally do;
6. Remove the Tuohy needle and connect the epidural filter to the catheter;
7. Administer a bolus injection of 5ml bupivacaine through the filter;
8. Connect the epidural pump line to the epidural filter. You do not need to start the infusion;
9. Disconnect the epidural pump line from the epidural filter and connect a cap to the filter.

**ICU / PACU Nurse Procedure (N1)**
The following instructions were given to each participant:

This patient’s name is Andrea Jones. She is 66 years old and has just had an abdominal hernia repair. She had an epidural catheter placed for pain management. The catheter was placed a short time ago and still is capped off. The MD physician has written instructions for pain management as well as IVs.

IMPORTANT: Please assume that all the pumps have been set at the appropriate flow rate. You do not need to set the flow rates yourself - just start the infusion. You can assume that all the vials are sterile.

Here are your instructions. Please carry out the instruction as directed by the moderator.

**Physician Instruction**

1. **Intravenous**
   - Draw up 1 ml of furosemide from the ampoule and give as an IV bolus over one minute.
     - You do not need to dilute the furosemide;
   - Start an IV infusion 0.9% normal saline at 100ml/hr;

2. **Epidural**
   - Give an Epidural bolus of 2ml of bupivacaine
   - Connect the epidural set to the epidural catheter filter and start the epidural infusion of bupivacaine at 10ml/hr;

3. **Enteral**
   - Flush the nasogastric tube with saline
   - Start tube feeding using the pump at a rate of 50ml/hr.

The order of parts 1 and 2 were randomly allocated; part 3 was always carried out last.

Each nurse participant was asked to complete a questionnaire after carrying out the procedure. The responses used the same rating scale as that used by the clinicians. They were also asked whether they had noticed any leaks and whether they would be happy to use devices fitted with the ISO 80369-6 connectors in their clinical practice.

The protocol used by three nurses towards the beginning of the study asked the nurses to deliver the furosemide ‘over 5 seconds’, as this was in the protocol originally agreed. This was amended to ‘over 1 minute’ for the remaining 14 nurses to reflect normal clinical practice; this change to the protocol was also agreed. However, it was not a requirement for successful injection of furosemide that it was delivered over 1 minute and the majority of participants delivered the furosemide in less than 1 minute, as reflected in Figure 34. There was no restriction on times for either of the other two sub-procedures.

**Cross-connection (PN2)**

The following instructions were given to each participant:

1. Attempt to connect each of the devices on the benchtop in front of you (working from left to right) to the non-Luer epidural connectors (male and female) attached to the short piece of tubing. Some of these connections are possible and others will be difficult or impossible.

2. After each connection, please inform the moderator how easy or difficult the connection was. The questions on the form are labelled with a letter from A to I which correspond to the labels on the table in front of you. The ease of connection is made on a five-point scale:
1. very difficult or impossible
2. difficult
3. so-so
4. easy
5. very easy

3. You can check whether a connection has been made by picking up the end of the tube opposite to that with the epidural connector - if the devices come apart under their own weight when held vertically, then the connection has not been made. If a connection has been made, you will be asked whether the force that you applied was force that you would be happy to use in clinical practice;

4. Move onto the next and subsequent connectors until all have been tested in this way and all questions answered.
Annex C - Equipment supplied and used for the study

Trays were provided for each participant for each procedure. The participant was asked to check the contents of the tray prior to starting the procedure. Each tray contained all of the items they would require for the procedure.

The items for the particular procedures are as follows:

**Spinal anaesthesia (P1)**

*Contents of the tray:*

For skin local anaesthetic

- Luer drawing-up needle
- 3ml lock syringe (option of slip syringe) for skin local anaesthetic
- ¾” 25G hypodermic needle
- ‘skin L.A.’ vial

For spinal injection

- Spinal needle, pencil point with integral stylet, length 90mm, 25G, with size-matched introducer needle (Luer and non-Luer supplied by BBraun/Pajunk)
- Choice of either 3ml and 5ml slip or lock syringes
  - Luer (BD Plastipak or BD Luer-Lok Tip)
  - non-Luer (lock syringes: Intervene; slip syringes: Neurax)8
- Drawing-up needles × 2
  - Luer (BD)
  - non-Luer (Intervene)
- Vials
  - ‘opioid’
  - ‘bupivacaine’
- Pad

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8 Slip syringes from Intervene were not supplied in time for the start of the study
Lumbar Puncture and Chemotherapy (P2)

Contents of the tray:

For skin local anaesthetic

- drawing-up needle (Luer) (BD)
- 3ml lock syringe (option of slip syringe) for skin local anaesthetic (BD)
- ¾” 25G hypodermic needle (supplied by Smiths Medical, US)
- 'skin L.A.' vial

For spinal injection

- Spinal needle, Quincke tip with integral stylet, length 90mm, 22G (Luer and non-Luer supplied by BBraun/Pajunk)
- 3ml and 5 ml lock syringes pre-filled with water and labelled ‘IT Chemotherapy 1’ and ‘IT Chemotherapy 2’
  - Luer (BD Luer-Lok Tip)
  - non-Luer (Intervene)
- 3-way tap
  - Luer (BMS Critical Care)
  - non-Luer (Neurax)
- Universal container
- Pad

Figure 47: Tray for P2 (chemotherapy injection) - Luer

Figure 48: Tray for P2 (chemotherapy injection) - ISO 80369-6

CSF Collection and Pressure Measurement (diagnostic lumbar puncture) (P3)

Contents of the tray:

For skin local anaesthetic

- drawing-up needle (Luer) (BD)
- 3ml lock syringe (option of slip syringe) for skin local anaesthetic (Luer) (BD)
- ¾” 25G hypodermic needle (supplied by Smiths Medical, US)

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9 3-way taps supplied by Intervene leaked and were replaced by Neurax taps for the remainder of the study
For spinal injection and pressure manometry

- Spinal needle, Quincke tip with integral stylet, length 90mm, 22G (Luer and non-Luer supplied by BBraun/Pajunk)
- Manometer
  - Luer with slip connector on 2-way tap (with ‘off’ lever) (Rocket Medical)
  - Non-Luer with locking connector on 3-way tap (Neurax, supplied by Rocket Medical)
- Universal container
- Pad

Epidural catheter placement and bolus injection (P4)

Contents of the tray:

For skin local anaesthetic

- Drawing-up needle (Luer) (BD)
- 3ml lock syringe (option of slip syringe) for skin local anaesthetic
- ¾” 25G hypodermic needle
- ‘skin L.A.’ vial

For epidural

- Loss-of-resistance syringe, 7ml slip
  - Luer (Smiths Portex, sourced locally)
  - Non-Luer (Smiths Medical, US)
- Tuohy needle 16G x 90mm
  - Luer (supplied by Smiths Medical, US)
  - Non-Luer (BBraun/Pajunk)

10 Manometers supplied by Intervene had a fixed, non-rotating locking collar, which the first participant carrying out this procedure found to be very difficult to use. Neurax manometers were used for the remainder of the study.

11 Luer Tuohy needles supplied by Smiths Medical were used as these had wings attached. The wings supplied by NCC UK Ltd did not attach securely to the Tuohy needles supplied by BBraun/Pajunk.
Usability study on ISO 80369-6 connectors (2014-12-31) - JWG4 N288
(replaces N285)

- Wings for non-Luer Tuohy needle (NCC UK Ltd)
- 5ml lock syringe
  - Luer (BD Luer-Lok Tip)
  - non-Luer (Intervene)
- Epidural catheter – Gauge to fit 16G Tuohy needle
  - Luer (supplied by Smiths Medical, US)
  - non-Luer (Teleflex Medical, supplied by Smiths Medical, US)
- Catheter introducer
  - Luer (supplied by Smiths Medical, US)
  - non-Luer (supplied by NCC UK Ltd)
- Tuohy Borst Adaptor
  - Luer (supplied by Smiths Medical, US), with 2ml slip syringe to open adaptor
  - non-Luer (Teleflex Medical, supplied by Smiths Medical, US)
- ‘0.2micron’ disc filter
  - Luer and non-Luer both supplied by Smiths Medical, US
- Drawing up needle
  - Luer (BD)
  - non-Luer (Intervene)
- Gallipot labelled ‘saline’
- ‘bupivacaine’ vial
- Pad

In addition, an epidural pump (McKinley Bodyguard 545) with appropriate administration sets (Luer and non-Luer versions supplied by Baxter) was made available to connect to the epidural catheter filter.

ICU /PACU Nurse procedure

A ‘fashion’ manikin (Songmics International) was arranged with an NIBP cuff, an oxygen facemask with oxygen tubing, an enteral feeding tube (Baxter) with ISO 80369-3 connectors, a peripheral IV catheter with octopus 2 bionector (Vygon) attached, a single lumen central line in the chest wall, an epidural line with filter with ISO 80369-6 connectors, and a Foley catheter with drainage bag.

Contents of the tray:
Usability study on ISO 80369-6 connectors (2014-12-31) - JWG4 N288
(replaces N285)

- 60ml enteral syringe pre-filled with 'saline' (water) (ISO 80369-3 connector) (Covidien)
- Drawing up needle (Luer) for IV (BD)
- 3 ml Luer syringe for IV (lock) (for 1ml furosemide) (BD)
- 5 ml slip Luer syringe (BD)
- Drawing up needle (non-Luer) for epidural (Intervene)
- 3ml 80369-6 syringe for epidural (lock) (for 2ml bupivacaine) (Intervene)
- 'Furosemide' vial
- 'Bupivacaine' vial

In addition, pumps were supplied for the IV infusion (Baxter Colleague CXE), enteral feed (Covidien Kangaroo) and epidural (McKinley Bodyguard 545), with the appropriate administration sets. Three bags labelled 'bupivacaine', 'saline' and 'enteral feed' were placed on a drip stand. The appropriate administration sets were placed in the pumps. The pumps were non-functioning, but the participants were asked to press the 'start' button on each pump to indicate that the pump had been connected and that that part of the procedure had been completed.

Figure 53: Tray for N1 - ICU/PACU nurse procedure.
Annex D - Comments from Participants

Comments on Procedures
1. All nurse participants were happy to give bolus injections of bupivacaine in the study. However, in normal clinical practice, it would be the clinician who would give a bolus injection using a syringe. The nurses would generally only give a bolus, if required, through the epidural pump. Therefore, the procedure given in the protocol was not their usual practice, and they would not be connecting and disconnecting needles and syringes for neuraxial procedures in their usual practice.

2. Although eight of the nine participants carrying out procedure P2 (lumbar puncture and chemotherapy) were happy to use a 3-way tap as part of the procedure (one participant did not want to use a 3-way tap as it was not part of her normal clinical practice), most commented that it was not part of their normal clinical practice, as the chemotherapy drug would get ‘lost’ in the deadspace of the 3-way tap so that it would not be delivered to the patient. This was particularly so for the tap with the ISO 80369-6 connectors, as it was longer than the Luer equivalent, and hence had a greater dead space. Although the delivery of two drugs from two separate syringes would involve the loss of a few drops of CSF whilst swapping syringes, this was considered by the participants to be acceptable clinical practice.

Comments on Equipment
1. The bore of the non-Luer drawing up needles appeared to be quite narrow, in that it took a comparatively long time for syringes to fill from the vials when using the needle. The users commented that ‘The drawing up needles should be better calibre (better flow).’ and ‘difficult to draw instillate up - entrains air’. On further questioning afterwards, the second participant commented that the appearance of entraining air was very likely due to the formation of a (partial) vacuum in the syringe due to the slow flow of liquid.

2. The epidural catheters were generally considered to be too soft (too flexible) making insertion through the needle and into the manikin difficult. Some participants commented that they could not see the meniscus in the catheters because of their design; the catheters were also found to be very stretchy, so that removal to the correct depth of insertion after removal of the Tuohy needle was difficult.

3. Two users commented that they would normally use 8 cm Tuohy needles rather than the 9 cm needles supplied for the study.

4. The wings on the Luer Tuohy needles were considered to be too small by three participants. The wings on the non-Luer Tuohy needles were separate components which needed to be fitted to the needles prior to use: five participants commented negatively on these wings, for example, that they were too loose or did not feel secure.

5. The Tuohy-Borst Adaptor supplied with non-Luer connectors was commented on negatively by nine of the nineteen participants carrying out the epidural procedure, generally because it operated using a very different mode of action to the adaptor supplied for the Luer arm of the study (and with which most participants were familiar) and many of these participants considered that the connection of the catheter in the adaptor was not secure and that the adaptor could be easily opened inadvertently.
Comments on Connectors

1. When asked the question ‘I believe that there are valid patient-safety reasons for replacing Luer connections with non-Luer connections in my area of clinical practice’, six participants (11%) replied ‘no’.

   a) For two participants, this was because their area of clinical practice was where needles and syringes would not be used by the participant (e.g. in ICU for bolus epidurals) or where fluid was being removed from patients rather than drugs being injected (e.g. CSF collection and pressure manometry);

   b) Two participants were not really sure about replacing the Luer connector;

   c) Two other participants considered that the Luer system was secure and familiar, for the latter so that the procedure could be completed more quickly;

   d) One participant replied ‘yes’ for epidurals but ‘no’ for spinals.

2. Some participants had taken part in studies on other non-Luer devices:

   a) One commented that the connectors were ‘Better than previous ‘new’ adapters I have tried over the last 4 years’;

   b) Another commented that the connectors were ‘Good - feel slightly easier (better connection) to current needles’;

   c) Another participant who was currently using the Surety system commented that ‘the drop collection [CSF collection] was much better than the Surety system’.

3. Participants’ comments on connectors were also collected directly after undertaking each procedure:

   a) One participant thought that there should be more differentiation between Luer and non-Luer spinal needles (clarified by the study coordinator - the 22G spinal needles both had black hubs and from a brief inspection looked the same. This was also true of the other needles.);

   b) One participant queried whether the connector on the introducer needle for the 22G spinal needle would be Luer or non-Luer for the new system. His current practice is to occasionally inject skin local anaesthetic through the introducer needle prior to placement of the spinal needle. Thus, for this particular user, the introducer needle has two possible functions (the prime function of introducing the spinal needle, and a secondary, off-label, use for injecting skin local anaesthetic) and use of the new connector on this device would prevent delivery of the skin local anaesthetic in this manner. Whilst the introducer needle on the non-Luer samples supplied for the study had Luer connectors, there is a view amongst some clinicians that the introducer should also be non-Luer to prevent accidental injection into the intrathecal space in thin patients.

   c) One participant commented that it was not so easy to differentiate between slip and lock syringes now that slip has a collar.

4. The last question ‘We value your opinion on these new connectors. Do you have any other comments to make?’ was an open question:
a) Three participants specifically mentioned that the yellow colour-coding was a good idea (two other participants specifically mentioned this in replies to earlier questions);

5. Participants were asked to imagine other circumstances where something could have gone wrong with the new connector:

a) One participant mentioned the spikes on the end of administration sets which could be inserted into any bag of fluid;

b) Two participants also mentioned that the wrong drug could be drawn up into the syringe;

c) Another participant commented that it would still be possible to use a needle to inject the contents of a syringe into a port.

d) One participant queried the additional cognitive workload associated with the introduction of a new connector and the risk of having two different systems in place;

Comments on Manikins

1. No comments were made by the nurses on the manikin used for the ICU / PACU (N1) study.

2. Comments made by participants using the spinal injection simulator were generally that the tissues were much stiffer than those found typically in clinical practice; this view was supported by the evidence from the study, as the spinal needles kinked occasionally as the procedures were carried out.

3. Many participants carrying out procedure P4 (epidural catheter placement and bolus injection) commented on the manikin, in particular that it was difficult to thread the catheter through into the intrathecal space (even though the intrathecal inserts had been removed from the manikins to facilitate this). In addition, one participant commented that because of the change to the manikin for the study it would be difficult/impossible to know if air is entering through a poor connection or from the open catheter.
Annex E - Results from Video Analysis

Videos recorded whilst the participants were carrying out the procedures were analysed following completion of the procedures. The following outcomes were recorded:

Procedures P1 to P4

- Time taken to prepare the tray before starting the procedure;
- Time taken to observe the appearance of CSF in the needle hub (P1 to P3);
- Glitches occurring during the procedure, including:
  - Leakage of injectate or infusate;
  - Leakage of spinal fluid;
  - Assembly problems;
  - Number of attempts to find the intrathecal or epidural space;
  - Insertion of sub-assemblies and accessories (for example, problems with re-inserting the stylet);
  - Connection and disconnection of the syringes without causing displacement of the needle in the intrathecal space;
- Overall time taken to undertake the task (injection, sampling, pressure measurement etc.);
- Assessment of the ability to collect CSF without contamination from spinal needles fitted with 80369-6 connectors.

Procedure N1

- Whether any confusion arose regarding the ability to identify which connectors are intended to mate together;
- Whether any cross-connections were attempted.

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12 A glitch is defined as ‘a deviation from the recognised process with the potential to reduce its quality or speed, including interruptions, omissions and changes, whether or not they affected the outcome of the procedure’.
Annex F - Samples supplied for the study

Needles
- 25G × 90 mm pencil-point spinal needles with introducer (Pajunk / BBraun) (Luer and non-Luer)
- 22G × 90 mm Quincke spinal needles (Pajunk / BBraun) (Luer and non-Luer)
- 16G × 90 mm Tuohy needles (Pajunk / BBraun) (Luer and non-Luer, non-Luer not used in the study)
- 16G × 90 mm Tuohy needle (Smiths Medical) (Luer)
- 25G × ¾” hypodermic needle (supplied by Smiths Medical) (Luer)
- Drawing-up filter needles (Intervene) (non-Luer)

Syringes
- 3ml and 5ml lock syringes (Intervene) (non-Luer)
- 3ml and 5ml slip syringes (Neurax, supplied by Hunter (non-Luer)
- Loss-of-resistance syringes (Smiths Medical) (non-Luer)
- 60ml enteral syringe (Covidien) (ISO 80369-3 connector)

Epidural kit
- Epidural catheter (Smiths Medical) (Luer)
- Epidural catheter (Teleflex Medical, supplied by Smiths Medical) (non-Luer)
- Wings for non-Luer Tuohy needle (NCC UK Ltd)
- Epidural catheter (Smiths Medical) (Luer)
- Epidural catheter (Teleflex Medical) (non-Luer)
- Epidural catheter guide (Smiths Medical) (Luer)
- Epidural catheter guide (NCC UK Ltd) (non-Luer)
- Touhy-Borst Adaptor (Smiths Medical) (Luer)
- Touhy-Borst Adaptor (Teleflex Medical) (non-Luer)
- 0.2 micron disk filter (Smiths Medical) (Luer and non-Luer)
- Epidural pump (McKinley Bodyguard 545)
- Administration sets (Baxter) (Luer and non-Luer)

Other components
- ISO 80369-6 male and female connectors attached to ~15 cm lengths of tubing (Smiths Medical)
- Infusion pumps (Baxter Colleague CXE)
- Enteral feeding pump (Covidien Kangaroo)
- Preparation trays (provided by Philip Bickford Smith)
- Saline vials (Baxter) (re-labelled ‘Skin L.A.’, ‘Bupivacaine’, ‘Opioid’ and ‘Furosemide’)
- Pads (Smiths Medical)
- 3-way taps (BMS Critical Care) (Luer)
- On/off tap (Neurax, supplied by Philip Bickford Smith) (non-Luer)
- Manometer with slip connector on 2-way tap (with ‘off’ lever) (Rocket Medical) (Luer)
- Manometer with locking connector on 3-way tap (Neurax, supplied by Rocket Medical) (non-Luer)
- Peripheral IV catheter (Terumo) (Luer)
- Catheter Extension set (Baxter) (Luer)
Usability study on ISO 80369-6 connectors (2014-12-31) - JWG4 N288
(replaces N285)

- Enteral feed connectors, male and female (Corpak) (ISO 80369-3)
- Foley catheter (Porges silicone Tiemann tip for majority of participants; Bard Foley tray supplied by Baxter for last few participants)
- NIBP cuff inflation tubing (4 different connectors of configurations described in ISO 80369-5):
  o B1-style male (Rectus);
  o B2-style female (Rectus);
  o B3-style male (CPC); and
  o Appendix H -style male (Clippard Cinti-O)
- Firtree connector (East Healthcare)
- Oxygen facemask and tubing (Baxter)
- Drapes (Baxter)
- Pads (Baxter)
- Gloves (nitrile powder free) (supplied by Baxter)

Manikins
- Spinal injection simulator (Model AN1036, Adam,Rouilly)
- Lumbar epidural injection trainer (Model APEIT100, Adam,Rouilly)
- ‘Fashion’ manikin (Songmics International)

Samples sourced locally
- 2ml and 5ml slip syringes (BD Plastipak) (Luer)
- 3ml and 5ml lock syringes (BD Luer-Lok Tip) (Luer)
- Loss-of-resistance syringes (Smiths Portex) (Luer)
- Drawing-up (blunt tip) filter and non-filter needles (BD) (Luer)
- 21G × 1½” hypodermic needle (BD Microlance) (Luer)
- Breathing system filter (Flexicare) (Luer)
- Gallipots
- Universal containers
- Octopus 2 Bionector (Vygon) (Luer)
Annex G - Cross-connection of ISO 80369-6 slip syringe with other devices

Introduction
During the study in Leicester, Paul Sharpe (Consultant anaesthetist, Chair of the NHS England Small Bore Connector Clinical Advisory Group, and lead clinician for the Leicester part of the study) suggested including ‘slip’ syringes with ISO 80369-6 connector in the cross-connection (NP1) part of the protocol. Although not part of the formal protocol agreed prior to the start of the study, ad hoc testing was carried out with an Intervene 5 ml slip syringe (which was not otherwise included in the study as the First Article Inspection (FAI) data was not available in time) and, later (which was not recorded on video) a Smiths Medical slip loss-of-resistance syringe (LOR), which was supplied for use during the epidural analgesia procedure.

Methods
Cross-connections were attempted between the Intervene syringe and the devices listed in the Methods section of this report. The syringe was pre-filled with water so that if a cross-connection could be made, an attempt was made to inject the contents into the other device.

Results
Secure cross-connections were made between the Intervene syringe and

- sampling port of the breathing system filter (rated 'easy'), water could be injected into the filter;
- inflation connector of the Foley catheter (rated 'easy'), water could be injected into the tube;
- ‘firtree’ respiratory connector nipple (rated 'easy');
- hypodermic needle (rated ‘so-so’), water could be injected through the needle, but with substantial leak.

In addition, the tip of the Intervene syringe could be placed into the injection port of the IV cannula, but a secure connection could not be made and liquid could not be injected through the cannula.

Further Testing
It was reported during the testing carried out in Leicester (although not captured on video) that the Smith Medical LOR syringe was more difficult to cross-connect with other devices than the Intervene syringe. The Smiths Medical LOR syringe is made from stiffer plastic than the Intervene syringe.

Further testing was therefore carried out in Bridgend and then in Bristol.

A paediatric oncologist in Bridgend was asked to try and connect both types of syringe to a hypodermic needle with a Luer connector. The participant used more force than in normal clinical practice but connected the Intervene syringe to the hypodermic needle and injected water through the needle, although there was an obvious leak at the connection between the two devices.

However, the participant was not able to connect the Smith Medical LOR syringe to the Luer needle.

The participant was also able to connect the Intervene syringe to the Luer lock port on an IV catheter (Terumo Versatus-W) and inject water through the cannula, although again there was an obvious leak.
leak at the connection between the two devices. According to the participant, the force used was 'a bit too much', and she also stated that the devices 'have to be put on at an angle ... not a normal way to put it on'. The participant was not able to connect the Smiths Medical LOR syringe to the IV cannula. During the subsequent discussion, the participant commented that the force used to try and connect the two devices would depend on where the connector for the IV cannula was placed; if it was placed on a patient's arm, a clinician would probably use less force to try and cross-connect the devices than if the connector was on the end of a flexible extension line.

Further tests were then carried out by two clinicians in Bristol. An IV cannula (Terumo Versatus-W) was strapped onto a manikin hand and the clinicians were asked to try and cross-connect both the Intervene and Smiths Medical -6 syringes with the main Luer lock port on the cannula. The first clinician failed to make a secure cross-connection and no liquid was injected through the cannula despite the use of excessive force.

The second clinician was able to make a secure connection between both syringes and the IV cannula. Although the connection was secure, water leaked out through the connection when the syringe plunger was depressed. However, some liquid did pass through the cannula. It was noted by the clinician that the force used to make the connection was greater than the force normally used in clinical practice, particularly with the LOR syringe, and, overall, the second clinician stated that the risk of misconnection was clinically acceptable. Furthermore, if a syringe with a central nozzle was used, the IV cannula would have to be lifted away from the patient's arm, reducing the risk of misconnection (this would not be the case when using a syringe with an offset nozzle). It was also noted that the risk of misconnection is reduced substantially if a needle-free connector (e.g. Octopus 2 Bionector) is connected to the IV cannula, as syringes with the ISO 80369-6 connector did not cross-connect with this type of connector.

**Comments**

Following this testing, discussions with members of the ISO 80369-6 Task Force and JWG4 took place, and work is currently underway to understand if it is possible to make any design changes which would reduce these cross connection opportunities further.

This work is being coordinated through the appropriate ISO groups.
Annex H - Equipment issues

3-way taps

During the initial usability testing in Bridgend, the Intervene 3-way taps were found to leak by both clinicians undertaking the oncology element of the testing (P2).

In one of the project group phonecalls, it was suggested that they be tested to the draft ISO 80369-20 test method.

SMTL tested some of the 3-way taps from Intervene which were found to be leaking by the clinicians, and other taps available from Neurax.

The taps were assembled and tested directly against the ISO-80369-6 needle hubs supplied by BBraun/Pajunk.

- 3-way tap without manometer (assembly at 27.00N axial, 0.1110 N.m torque) and pressurised at 300-310kPa.
  - After 9 secs - liquid seen seeping out of hub; drop fell at 10 secs. FAIL
- 3-way tap with manometer (assembly at 27.12N, 0.1005 N.m torque) and pressurised at 300-310kPa
  - After 8 secs - liquid seen seeping out of hub; drop fell at 12 secs. FAIL
- Rotating collar sample - Neurax
  - 3-way tap with manometer (assembly at 27.20N axial, 0.1100N.m torque, and collar tightened to 0.1005N.m)
    - No leakage after 30secs @ 300-310kPa. PASS
- Rotating collar sample - Neurax
  - 3-way tap (no manometer) (assembly at 27.30N axial, 0.1095N.m torque, and collar tightened to 0.1055N.m)
    - No leakage after 30secs @ 300-310kPa. PASS

Decision

Based on this data it was concluded that the observations of the clinicians and the laboratory testing indicated that the tap performance was not acceptable, and that continuing to use them in the study may prejudice the study.

The Neurax devices, whilst known to be outside the dimensional limits of the current ISO draft 80369-6, have almost identical characteristics to the -6 design, and are functionally acceptable.
## ISO 80369-6 Usability Protocol First Article Inspection of Components: Female Connectors

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<th>D</th>
<th>E</th>
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Rationale for lack of conformance to key dimensions for first article inspection

Note: no dimensions are included for the two way or three way stopcocks. The Neurax stopcocks were used in the testing but the company was not able to supply first article dimensions of the parts.

All of the female connectors met all requirements for the first article inspection. Of the male connections, two parts had dimensions which did not meet ISO requirements as defined in the draft DIS ISI-TC210-JWG4_N574_Small bore connectors part 6: Connectors for neuraxial applications dated 26 JUN 2014. The two parts which did not meet specified dimensions from 80369-6 Annex were the male connector for the infusion line and slip male syringes made by Neurax.

The male connector was out of dimensional specification in dimensions h & j. These are the dimensions for the minor and major thread diameters in the male connector. The mold making these parts was originally developed as a prototype mold for the maximum material conditions so the ISO team could physically test parts molded at the limits of the tolerances. The mold was made prior to identifying interconnection problems and was therefore made to a thinner thread dimensions. The tool was designed to achieve the limits of the tolerances; not the nominal dimensions. Some under specification or over specification dimensions were acceptable since the parts were meant to challenge the limits of the specifications. In June 2014, the ISO committee recommended changing the wall thickness of the threads to improve the resistance to interconnection. The maximum material condition mold was making parts in which the threads and the conical dimensions, d and g, were in dimensional tolerance. The team agreed to deviate and allow slightly smaller “j” and “h” dimensions since it was not practical to create another mold to fix these issues.

The slip male syringes made from Neurax were out of dimensional tolerances for both of the conical dimensions “d” and “g” as well as the depth of the threads “e”. These syringes were originally developed as a non-Luer alternative in the U.K. The design is similar although not identical to the ISO 80369-6 connectors. Due to confusion, the -6 syringes were not ready when the study started and the study coordinators asked if the Neurax slip syringes could be substituted for the planned Surety slip syringes. To evaluate whether the parts which were out of dimension were acceptable, the task force members tested thirty each of the Neurax slip syringes in two different sizes; 3 and 5 ml. The results are summarized in attached report ETR-350 “Neurax Syringe Testing 7 JUL 2014”.

Three different tests were performed, subatmospheric leak, falling drop leak and resistance to axial loading. All thirty syringes in both sizes passed both leak tests. Several of the syringes did not pass the axial separation test results and these failures are rationalized in attached report ETR-350 Neurax Syringe Testing 7 JUL 2014. The syringes are acceptable for use since the failure mode in the human factors evaluation is minor; the user will have to re-attach Neurax syringes which separate at lower than desired forces.
APPROVALS

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REVISION HISTORY

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1 PURPOSE
The purpose of this ETR is to test two sizes of Neurax syringes, that do not meet all of the ISO 80369-6 dimensional specifications to see if they still meet the the ISO 80369-6 performance requirements. Successful performance of these syringes could provide evidence to support opening some of the dimensional specifications in the 80369-6 ISO spec.

2 SCOPE
The Neurax syringes were tested to three of the ISO 80369-6/-20 specifications to see if they meet the performance requirements. The three ISO specs are: Annex C - Falling Drop Positive Pressure Liquid Leakage, Annex D - Sub-Atmospheric Pressure Air Leakage, and Annex F - Resistance to Separation from Axial Load.

3 APPLICABLE DOCUMENTS

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3.1 Definitions

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4 EQUIPMENT AND MATERIALS

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4.2 Materials
- Neurax 3-ml, Non-Luer, Slip, Syringes (30 syringes tested) natural polypropylene
- Neurax 5-ml, Non-Luer, Slip, Syringes (30 syringes tested) natural polypropylene
- Yellow MMC Polycarb 80369-6 connectors from Mold# 130152, WO# 28481721; yellow Makrolon RX 1805
- 3D printer parts used as holding fixtures for the TR ATS-130.

4.3 Software
- CTS software
- Crescent software
- TR ATS-130 software

5 BACKGROUND
There was confusion about the devices required for testing during the ISO human factors evaluation. The syringe manufacturer thought that the human factors testing would only require locking syringes. Locking syringes were ready for the start of the evaluation. The committee which authored the protocol specified both locking and slip syringes to be tested. The requirement for slip syringes was not known until six weeks prior to the start of the human use protocol. Once the requirement was known, the syringe manufacturer built tooling for the slip syringe but the parts were not available when the actual testing was set to begin.

The committee inquired if they could substitute Neurax slip syringes for the procedure which initiated this test report. The human factors study was a critical deliverable for the ISO 80369-6 draft DIS which was anticipating voting would be complete in November 2014. Therefore delaying the start of the testing to await the -6 slip syringes was putting at risk the data which ISO voting members would need to make their decisions about the standard. After reviewing the data contained in this report, the committee decided that the risk of delaying the human factors evaluation was not warranted since the Neurax syringes were leak free. The only risk was with premature disconnection due to an applied axial load which is discussed in section 7 of this report.

# 6 TEST PROCEDURES

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<td>C:\MTL32_2020\Data\Annex F SLIP asy Saltzman.tbm</td>
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Parameters | 27.5 N (max) for 5s (min) while rotating 90° (max) at 0.1 N·m (max) | Same as Annex D | Same as Annex D
---|---|---|---

Test

Equipment | Cincinnati - CTS Black Belt | Crescent | TR ATS-130

Program | 3 ml = P26, 5 ml = P27 | Yes | Variable_Annex_F_Saltzman_mod

Parameters | Shall not leak by more than 0.005 Pa·m³/s while being subjected to an applied subatmospheric pressure of between 80.0 kPa and 88.0 kPa over a hold period of between 15 s and 20 s. Shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. Shall not separate from the reference connector while being subjected to a disconnection applied axial force (applied at approx. 10 N/s) between 23 and 25 N over a hold period between 10 s and 15 s for a SLIP CONNECTOR | Specification | < 0.005 Pa·m³/s leak rate | No leak at 330 kPa for 35 s | No disconnection at axial tension 15 s @ 25N @ ~ 10 N/s

6.1 Test 1 Description – Sub-Atmospheric Pressure Air Leakage

6.1.1 Assembly per: ISO/DIS 80369-20, Annex D – Sub-Atmospheric Pressure Air Leakage

6.1.2 Test & Acceptance Criteria per: ISO/DIS 80369-6, Section 6.3 Leak rate less than 0.005 Pa *m³/s

6.1.3 Results:
6.1.3.1 3 ml : Thirty of thirty units passed
6.1.3.2 5 ml : Thirty of thirty units passed
6.1.3.3 The results were compared to the acceptance criteria of 0.005 MPa *m³/s and graphed in Figure 6.1. Both syringes were well above the required upper specification limit.
Subatmospheric leak rate of 3 ml, 5 ml Neurax syringes (<0.005 Pa*m^3/s)

3 ml


5 ml

Figure 6.1 Results of Subatmospheric leak

6.2 Test 2 Description – Falling Drop Positive Pressure Liquid Leakage

6.2.1 Assembly per: Annex C – Falling Drop Positive Pressure Liquid Leakage

6.2.2 Test & Acceptance Criteria per: ISO/DIS 80369-6, Section 6.2.3 no falling drop at

6.2.3 Results:
6.2.3.1 3 ml: Thirty of thirty units passed
6.2.3.2 5 ml: Thirty of thirty units passed

• 5 ml syringe #40 failed at the rubber stopper on the plunger, NOT at the slip interface. Therefore this is not considered a failure.

6.3 Test 3 Description – Resistance to Separation from Axial Load

6.3.1 Assembly per: Annex F – Resistance to Separation from Axial Load

6.3.2 Test & Acceptance Criteria per: ISO/DIS 80369-6, Section 6.5 (> 25 N for slip)

6.3.3 Results:
6.3.3.1 3 ml: 5 syringes (16.7%), #s 4, 9, 12, 17, and 30 did not pass the test. The data is illustrated in Figure 6.3.

6.3.3.2 5 ml: There were issues with the test apparatus for several of the samples.
- It is clear from reviewing the detailed log files that the test was not performed correctly (either due to operator error or equipment error) on syringe samples 66 through 71. The results for those samples will be excluded from the data analysis.
- At that point the test program was reset. It was also noticed by one of the test technicians that the test apparatus appeared to be out of alignment. After resetting the test program and correcting the alignment, the testing continued. All units not affected by the testing glitch passed.
- The data is illustrated in Figure 5.3. The 3 ml slip Neurax syringe showed poor capability.

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**Figure 6.3 Axial Separation Forces Neurax Slip Syringes**

7 DISCUSSION

The 3-ml and 5-ml syringes passed 2 of the 3 ISO tests. The 2 tests that passed were Falling Water Drop and Sub-Atmospheric Pressure. There were some failures of the Axial separation test.

These parts are acceptable for use in the human usability testing. According to the leak test data, parts will not leak. However the Neurax syringes are showing poor capability for axial separation. The first article inspection data indicates that the taper dimensions are not compliant with ISO specifications. See figure 7.1 which illustrates the dimensions which are not in conformance. Dimension “d” illustrated in figure 7.1, is consistently oversized while dimension “g” is close to and in one case exceeding the upper specification limit. This indicates the cone has a slightly smaller taper angle than is required by the standard. This slightly smaller taper angle is causing lower than desired axial separation forces.
ISO 80369-6 Usability Protocol First Article Inspection of Components: Male

The axial separation results indicates that the Neurax design is not suitable for long term use as the separation force data does not show compliance to the ISO 80369-6 requirements. However the Neurax syringes and other 80369-6 devices do connect together well and seal effectively. The most likely failure mode from the human factors evaluation based on the marginal axial separation data is user may connect the slip syringes and find the syringes pull apart more easily than is desired. However this connection force does not pose any clinical hazards since the devices will not be used clinically. If the devices disconnect prematurely during the human factors evaluation, the user will probably try to reconnect with higher forces. The test data indicates that if users use a higher load force than the 27N which is specified for axial separation testing, the parts will remain connected with higher axial separation forces. Hence a failure mode will be that the devices separate after connection and if this happens, will require a re-connection. Devices built according to the standard should comply with the minimum 25 N separation force requirements when the dimensions d and g are within specification.

8 ATTACHMENTS

Appendix A - Test Data
## Annex F - Axial Separation

### Neurax 3 ml Non-Luer Slip

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<th>Syringe</th>
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- **Min:** 18.9
- **Avg:** 27.5
- **Max:** 37.7
- **StdDev:** 5.271

### Neurax 5 ml Non-Luer Slip

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- **Min:** 27.6
- **Avg:** 34.6
- **Max:** 39.8
- **StdDev:** 3.106
## Annex D - Subatmospheric Air Leak

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Test date: 28-Jul-14

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<th>Notes</th>
<th>Syringe</th>
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**Min**: -0.0168 0.1340 2.87E-06  
**AVG**: -0.0109 0.1530 1.83E-05  
**Max**: -0.0017 0.1996 2.84E-05  
**StDev**: 0.0043 0.0151 7.29E-06

**Note 1**: Heard a "snap" during assembly - most likely deforming the syringe barrel

---

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### Annex C - Falling Water Drop

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### Test Resources Details

TestResources Model 250XV Equipment # E5350
TestResources program: C:\MTL32_2020\Data\Annex F slip assy Saltzman
TestResources Data file: C:\MTL32_2020\Saltzman\ETR350\ETR350 3ml syringe
TestResources Data file: C:\MTL32_2020\Saltzman\ETR350\ETR350 5ml syringe

Note 2: 5ml syringe #40 Failed at the rubber stopper on the plunger not at the SLIP interface.