ROUND TABLE REPORT

‘We cannot stop the train’

New systems in regional anaesthesia
Delegates

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The Faculty first considered general inhibitors of a wider use of regional anaesthesia (RA), of which shortage of educational programmes, skills training and technical competence topped the list. Their perspective was that there was not a sufficient number of experts in the techniques, and that training of surgeons/anaesthetists/ doctors might better be provided or supported by Industry.

One Faculty Member was able to cite the example of an ultrasound RA workshop that had succeeded in changing daily clinical practice in some countries, but that one- or two-hour workshops are not enough: you need a properly structured education programme. It was remarked that surgeons in the US may be viewed as blockers, because they perceive RA to be a time-consuming process, that impacts their ability to perform the surgery efficiently. Faculty recommended a well-structured curriculum with step-by-step, teach-the-teacher approach, with progressive implementation of different technical and level of knowledge and techniques, possibly involving cadaver training.

The discussion then moved to a focus on NRFit™, beginning with an analysis of a systematic literature review of anaesthesia misconnections, and following with an introduction to ISO 80369-6 design standard for neuraxial applications connection (NRFit™), the BD NRFit™ value offer, reflections on the current status of NRFit™ guidance and consideration of how to raise NRFit™ awareness.

### Safe and secure neuraxial connections: a systematic literature review of misconnections

Setting the scene for a Faculty discussion on NRFit™, BD presented the results of a systematic literature review of neuraxial and peripheral nerve block misconnections reported in case reports between 1999 and 2019. As assigned by specific inclusion and exclusion criteria, the summary of findings was based on 72 papers reporting a total of 133 cases related to misconnections, rated in terms of severity. Misconnections relating to IV medication to epidural and intrathecal routes were the most frequent (see Figure 1).

Factors contributing to connection-related injuries included the universal application of Luer adaptors, workarounds, stress/fatigue, environmental factors, failure to check or trace connections during patient transition and suboptimal reporting of adverse events or near misses.

Looking in detail at the number, severity and route of drug administration errors, caused by misconnection with more than two case reports we see that there were 24 reported deaths:

<table>
<thead>
<tr>
<th>Connection Type</th>
<th>Number (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural medication to IV route</td>
<td>38</td>
</tr>
<tr>
<td>IV medication to epidural route</td>
<td>38</td>
</tr>
<tr>
<td>Intravenous medication to intrathecal route</td>
<td>33</td>
</tr>
<tr>
<td>Peripheral nerve block medication to IV route</td>
<td>17</td>
</tr>
<tr>
<td>IV medication to extra/intraventricular route</td>
<td>4</td>
</tr>
<tr>
<td>Intramuscular medication to intrathecal route</td>
<td>1</td>
</tr>
<tr>
<td>Topical medication to intrathecal route</td>
<td>1</td>
</tr>
</tbody>
</table>

**References**
A summary of the literature review indicated the need for a solution to the incidence of misconnections:

- The number of occurrences is low: 1.3 – 2.7% of all identified anaesthesia medical errors, which equates to 1.0 – 1.1 occurrences per 10,000 anaesthesia administrations.
- However, the effects can be severe, leading to death.
- Connection errors are largely preventable.
- Chronic underreporting of misconnection errors is widely acknowledged.

**Introduction to ISO 80369-6 design standard for neuraxial applications connection (NRFit™)**

There was unanimous familiarity with the ISO of not to 80369-6 standard across the Faculty, and Professor Benhamou recounted the background to its development.

There is no one system that can avoid all errors, and it is absolutely necessary to combine several systems. As an indication of the scale of the problem, it is estimated that 14% of drug errors result from incorrect route of administration. Measures that have the potential to make systems less error prone and to enhance a culture of safety include organisational changes, communication and teamwork, teaching and research and audits. Those measures that are based on technology and equipment include the use of pre-filled syringes, international colour codes, calculators at bedsides, barcoding, the automatic recording of records and those functions that are obligatory. It was the NHS Patient Safety Alert 21 published in 2007 calling for safer practice with epidural injections and infusions that awakened healthcare professionals to the scale of the problem for RA. By 2011, all intrathecal bolus doses and lumbar puncture samples using syringes, needles and other devices in the UK were not to be connected with intravenous Luer connectors. In 2013 this was extended to all RA systems, not only neuraxial but also peripheral neural blocks and infusion boluses. To allow for hospital implementation time, manufacturers were obliged to supply devices with safer connectors well before the required implementation date in 2017. However, as we will see later, adoption by hospitals has been slow.

The ISO joint working group proposed the name NRFit™ to describe the 80369 series of non-Luer connectors. It is a series of different connectors, of which 80369-6 applies to all needles and syringes used for RA, encompassing spinal, epidural anaesthesia, combined spinal-epidural anaesthesia, peripheral nerve blocks and lumbar puncture. NRFit™ is colour coded yellow, reduces the risks of misconnections for neuraxial and regional blocks and is compatible between all manufacturers. (This specific colour is not included in the definition if the 80369-6 series but is acknowledged by manufacturers and healthcare providers as being a useful adjunct which might provide additional safety benefit.)

**TABLE 1**

**Number, severity and route of drug administration errors caused by misconnection**

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Drug class</th>
<th>Events (n)</th>
<th>Low</th>
<th>Moderate</th>
<th>Severe</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vincristine*</td>
<td>Chemotherapy</td>
<td>19</td>
<td></td>
<td></td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Thiocolchicoside*</td>
<td>Muscle relaxant</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Potassium chloride*</td>
<td>N/A</td>
<td>6</td>
<td></td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Local anaesthetic</td>
<td>5</td>
<td></td>
<td>1</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Tranexamic acid*</td>
<td>Antifibrinolytic</td>
<td>2</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Gadolinium*</td>
<td>Contrast agent</td>
<td>3</td>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ropivacaine</td>
<td>Local anaesthetic</td>
<td>3</td>
<td></td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Vecuronium*</td>
<td>Muscle relaxant</td>
<td>3</td>
<td></td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Paracetamol*</td>
<td>Pain reliever</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytocin</td>
<td>N/A</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Ephedrine*</td>
<td>Nonselective adrenergic agonist</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Succinylcholine*</td>
<td>General anaesthetic</td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiopental*</td>
<td>General anaesthetic</td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* indicates a drug that is not included in the definition if the 80369-6 series but is acknowledged by manufacturers and healthcare providers as being a useful adjunct which might provide additional safety benefit.

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It’s about sharing the message of the importance of [NRFit™], why it’s needed and educating people with the new protocols and the requirements behind it.

*Laura Mitchell*
We cannot stop the train – more or less every clinic in Europe and around the world has to adopt the new system

Paul Kessler
Clinicians often do not want to change what works for them: there are logistical barriers, changes to working procedures, and the general resistance to change. Those major barriers that would have to be overcome to enable conversion included unclear benefits and conversion challenges, followed by cost (although most costs in hospital are staff related) and the perception that there is no safety problem that need solving.

There is currently limited awareness of NRFit™ amongst healthcare professionals. There is also currently limited perception of the need for NRFit™, and Faculty Members summarised the need for NRFit™ to other healthcare professionals as ‘the need to avoid potentially fatal but easily preventable complications so as to provide assurance for the patient and for the hospital’.

The Faculty agreed that the main target audience for an NRFit™ awareness campaign would be anaesthetists (heads of departments and specialists involved in RA and neuraxial procedures) and hospital management (managing directors and manager administration). Pharmacists were also added to the target audience, as they have an interest in medication errors and patient safety. It was thought, in any case, that transition would be slow but exponential.

A multi-modal information system would be the best way to reach individuals, starting at big specialty meetings. And scientific articles written by decision makers are very influential.

There was a consensus that a balanced, narrative review, co-authored by the Faculty and possible experts in the US, Asia and the Far East, should be created.

**Conclusions**

Key messages and recommendations from the Board included the following:

- Educating and training anaesthetists on RA is paramount. Faculty recommended a well-structured curriculum with step-by-step, teach-the-teacher approach, with progressive implementation of different technical and level of knowledge and techniques, possibly involving cadaver training.
- There is a need for a European survey of current procedure-based RA practices, and where these practices might be headed in the future.
- A European Registry of misconnections, perhaps in coordination with ESRA and National Societies, would support the argument for the benefits of NRFit™.
- A balanced, narrative review published in a peer-reviewed Medline-cited journal could be part of a multi-modal NRFit™ awareness-raising campaign.

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