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ROUND TABLE REPORT

‘We cannot stop the train’

New systems in regional anaesthesia

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The BD Regional Anaesthesia Clinical Advisory Board Virtual Meeting was held on 23 – 24 July 2020 and was attended by anaesthetist and nurse representation from across Europe. The meeting focussed on the application of regional anaesthesia techniques and the implementation of the NRFit™, an alternative to the standard Luer connectors for peripheral, intrathecal and epidural procedures.

This report summarises the key findings and recommendations.

Emphasis on education and training

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.

Consider development of well-structured step-by-step curriculum

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

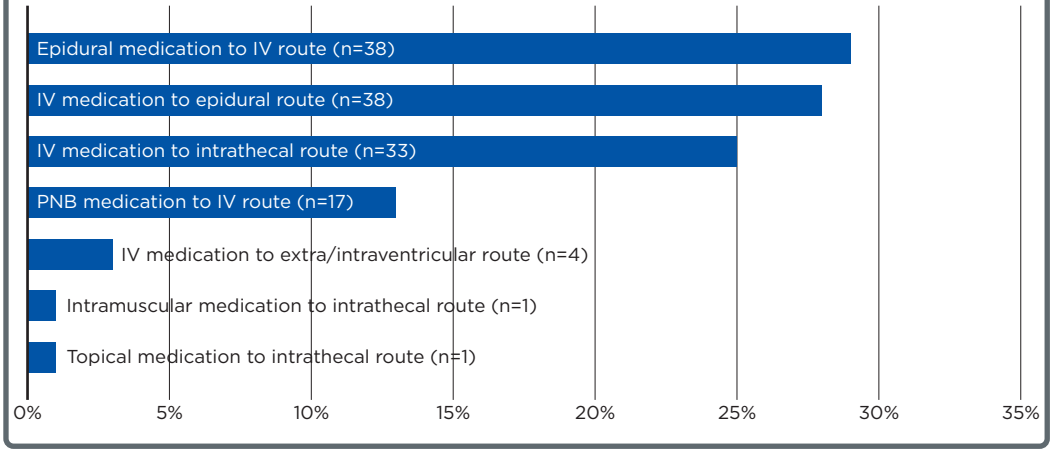
Setting the scene for a Faculty discussion on NRFit™, BD presented the results of a systematic literature review of neuraxial and peripheral nerve block misconnections reported in case reports between 1999 and 2019.[1] As assigned by specific inclusion and exclusion criteria, the summary of findings 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: >

FIGURE 1

Neuraxial and peripheral nerve block misconnections reported in case reports between 1999 and 2019[1]



References
1 Viscusi E.R., Hugo V., Hoerauf K., Southwick F.S. Neuraxial and Peripheral Misconnection Events Leading to Wrong-Route Medication Errors: A Comprehensive Literature Review. Regional Anesthesia & Pain Medicine. 2020 in press

TABLE 1

Number, severity and route of drug administration errors caused by misconnection[1]

Event severity scale			Incident(s)			
Drug name	**Drug class**	**Events (n)**	**Low**	**Moderate**	**Severe**	**Death**
Vincristine[a,b]	Chemotherapy	19			**4**	**15**
Thiocolchicoside[a]	Muscle relaxant	4				**4**
Potassium chloride[a]	N/A	6		**5**	**1**	
Bupivacaine	Local anaesthetic	5	**1**			**4**
Tranexamic acid[b]	Antifibrinolytic	2	**1**			**1**
Gadolinium[c]	Contrast agent	3		**1**	**2**	
Ropivacaine	Local anaesthetic	3	**1**	**2**		
Vecuronium[a]	Muscle relaxant	3	**1**	**2**		
Paracetamol[a]	Pain reliever	2		**1**	**1**	
Oxytocin	N/A	2		**2**		
Ephedrine[a]	Nonselective adrenergic agonist	2	**2**			
Succinylcholine[a]	General anaesthetic	2	**2**			
Thiopental[a]	General anaesthetic	2	**2**			

> “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*

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.) Research conducted by BD indicates that general attitudes

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

More cases

Wrong-route errors
IV to:
[a]Epidural
[b]Intrathecal
[c]Intraventricular/ extraventricular
Epidural to IV

Fewer cases

'We cannot stop the train'

Prioritise patient safety as a benefit of NRFit™

Call for EU Registry of misconnections

toward the ISO standard among anaesthetists is mixed, and that it is trying to solve problems they do not have, ie. they do not make mistakes, and that they prefer to use those systems on which they have been trained. They require easy identification of the differences between neuraxial connection types and should be able to identify a device specific to neuraxial applications.

There was unanimous support among the Faculty for the rigorous testing to which BD has subjected NRFit™ regarding torque and force required for proper placing of needles, stressing the importance of using the minimal amount of force to get a proper connection. There was agreement among the Faculty that implementation of the standard within one institution at a time should be the first goal, and that wider implementation, say within and across countries, will take time.

The Faculty shared their insight into the impact that NRFit™ might have on their patients and their practice. There was agreement that implementation would confer a potentially significant safety implication, but that the transition might be complicated and protracted. Controversies regarding winning over anaesthetists notwithstanding, there was the view that 'we cannot stop the train' in view of the fact that so many organisations and societies are pushing for something to be done regarding the safety of current connectors: Europe has to change and adopt the new system.

Regarding anaesthetist preferences, it was agreed among the Faculty that Luer Lock connection requires too much manipulation, and that they would be amenable to transitioning to Luer Slip connection for single shot and catheter, while perhaps retaining the Luer Lock for continuous applications, because it's safer regarding disconnection.

Current status of NRFit™ guidance

In response to a pre-Board Faculty questionnaire, it was learned that NRFit™ is currently being used by only one member from the UK, and its use is not yet widespread in the UK. It is being used mainly for spinals and some for PNBs, but the adoption is still very much in transition phase. Based on the experience from the UK delegate, clinicians are coming to terms with changing the way they work, and it is important that they be absolutely comfortable with the new systems. Nobody likes changes being made without their having been consulted, and the transition does cause some anxiety. In addition to the logistical and changeover problems, there were some instances of staff members finding workarounds. These and other transition issues are captured by a governance team, and addressed in route cause analysis, and learnings are cascaded back to all teams.

Also part of the pre-work was the question whether misconnections are monitored. It was ascertained that there is some monitoring, but it is neither routine nor mandatory. The consensus was that it would be good idea to have a European registry of misconnections, despite the fact that it is likely to run into problems of inconsistent methods and underreporting. Such a registry would best be done in association with ESRA through National Societies, so as to eliminate perception of industry bias.

Raising awareness of NRFit™

The raising awareness session was approached in three sections: (1) how to enable drivers to overcome barriers to the uptake of NRFit™, (2) how to summarise the need for NRFit™, and (3) what would comprise a strategy for raising awareness.

Patient safety was the overwhelming key driver to impact the conversion to NRFit™, followed by training and product information. Other drivers included evidence of a reduction in complications, ease of introduction and cost-effectiveness.

Rating the impact that a range of drivers would have on conversion, manufacturer readiness and European Directives were rated most highly, followed by clinical standards and recommendations, and clinical evidence.

There was divided opinion among Faculty Members on the need for further clinical evidence; some believed that the clinical evidence was clear, and that a transition to NRFit™ can reduce the number of wrong infusions. In 2017 the German Society of Anaesthesiology recommended the change to NRFit™, but at that time the products were not available and there was little pressure to do so. Even as companies can assure product supply, because a recommendation is not mandatory, uptake has been slow. It might help if a recommendation could come from ESRA or individual European Societies. In the case of Nottingham Hospital, which has trialled NRFit™, the key driver is patient safety to avoid near misses, clinical incidences and never events. But nobody really likes to change and the real, enduring motivational driver will be those people who believe in it.

Switching to identification of key barriers to conversion, availability of product and evidence resonated with everyone.

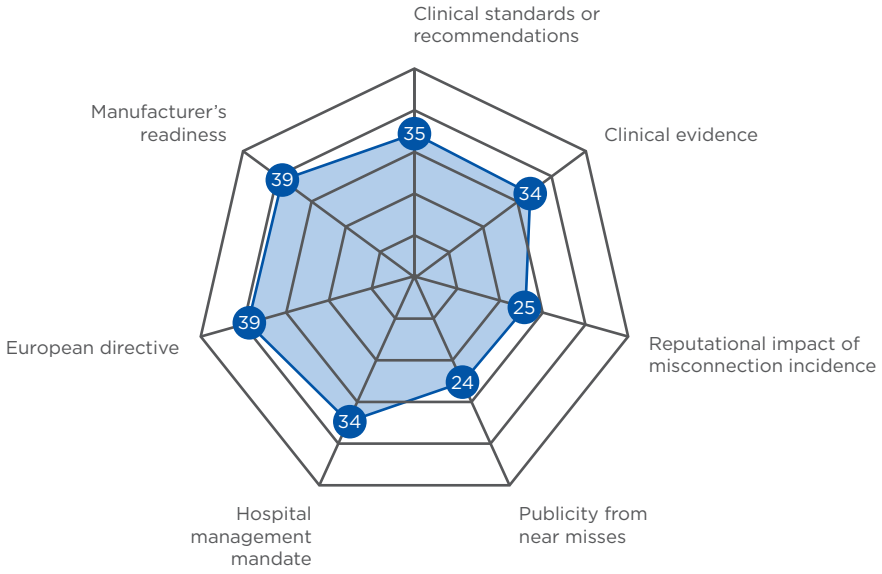
Potential impact of NRFit™ on patient care and practice

>

> [on the need for NRFit] ... the need to avoid potentially fatal but easily preventable complications, so as to provide assurance for the patient and for the hospital *All*

FIGURE 2

The faculty was asked to rate how the following drivers would impact conversion to NRFit™



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'.

Target anaesthetists

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.

Call for narrative review

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.

Three key barriers for conversion to NRFit™

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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