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To NRFit or not to NRFit?

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Abstract

Drug errors cause 700 deaths a year and could also be a factor in between 1,700 and 22,300 other ones in the UK. It is supposed that The ISO 80369-6 connector (NEFit) provides a simple way to reduce the risk of neuraxial misconnections and improve patient safety. However, it is a big mistake in the UK like that related to the Woolley and Roe case from Oct 13th, 1947 at the Chesterfield Royal Hospital, England.

A simple NRFit replacement is suggested: Every epidural infusion or intravenous infusion should be inspected and signed by 2 medical professionals- doctor or nurse (like it is the rule worldwide for giving blood and blood components).

Keywords: NRFit; Epidural; Spinal; Intravenous.

Drug Errors in England Cause Appalling Levels of Harm and Deaths

GPs, pharmacists, hospitals and care homes may be making 237 million errors a year - the equivalent of one mistake made for every five drugs handed out. The study said most caused no problems, but in more than a quarter of cases the mistakes could have caused harm.

Drug errors could be a factor in thousands of deaths a year.

The mistakes include:

- Wrong medications being given
- Incorrect doses dispensed
- Delays in medication being administered

The researchers - drawn from Manchester, Sheffield and York universities - acknowledge that there is limited data in this area so the figures are very much best estimates based on previous research, some of it going back years. They estimate that drug errors cause 700 deaths a year and could also be a factor in between 1,700 and 22,300 other ones. A fifth of the mistakes related to hospital care, including errors made by doctors administering anaesthetic before surgery. The rest were pretty evenly split between drugs given in the community by GPs and pharmacists, and those handed out in care homes. In total 1.15 billion drug prescriptions are made each year [1].

Why should we Adopt the New 80369-6 Connector?

The ISO 80369-6 connector provides a simple way to reduce the risk of neuraxial misconnections and improve patient safety. The new connector reduces the chance of an unintentional cross-connection with any other connector intended for non-neuraxial routes.

In some countries, the legal systems expect clinical staff to take all reasonable steps to mitigate the risk of cross-connection incidents, and

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therefore may expect clinical staff to use devices that use these application specific connectors. Non-adoption of the new connectors may expose clinical staff and organizations to legal challenges if further wrong-route incidents take place which could have been prevented by use of ISO 80369-6 compliant devices [2].

Is it mandatory to transition to the new ISO 80369-6 connector?

This varies by jurisdiction. For example, in California all epidural use must be transitioned by January 1, 2017. In the UK, the National Health Service (NHS) has already started planning for the introduction of 80369-6 connectors within 6 months of the California deadline.

In Europe and other markets throughout the world, many manufacturers and suppliers are following the subject closely, and plan to adopt the same new global standard connector system. The deployment of devices with the 80369-6 connector may be on different timelines in different global markets, but the goal remains the same-to align to a common neuraxial connector across the globe to improve patient safety [3].

ISO 80369

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from inappropriate medication, liquid nutritional formula, or air being administered neuraxially. Many incidents have been reported leading to international recognition of the importance of these issues and a need has been identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver fluids in other APPLICATIONS.

The ISO 80369 series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs and dimensions of SMALL-BORE CONNECTORS to ensure that

- They do not misconnect with other small-bore connectors, and
- They safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS. This part of ISO 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended to be used in neuraxial APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

There is international evidence that 'wrong-route' medication errors with neuraxial MEDICAL DEVICES have caused deaths and severe HARM. There are reports of non-epidural medications being administered into the epidural space and local anaesthetic solutions intended for epidural administration being administered by the intravenous route [4-8]. There is also a report where an anaesthetic agent for intravenous use was administered into the cerebrospinal fluid via an external ventricular drain and earlier reports of antibiotics being inappropriately administered by this route [9].

In July 2007, the World Health Organization's World Alliance for Patient Safety issued Alert 115 describing four incidents in different countries in which vincristine had been accidentally administered by the intrathecal route instead of intravenous route, as intended [4]. The Alert indicated that, since 1968, this same error had been reported 55 times from a variety of institutional settings.

These incidents occurred despite repeated warnings of the RISK and the introduction of extensive labelling requirements and recommendations, intended to standardize practice and reduce RISKS. Other health organizations around the world have also issued detailed guidance to minimize the RISK of these 'wrong-route' errors [5,7,10,11].

Nevertheless, reports of fatal incidents following the administration of vinca alkaloids continue to be reported internationally [12]. In 2009, the Food and Drug Administration in the USA issued a Medical Devices Calendar, which included an example of a case study of a neuraxial misconnection [13].

Small Bore Connectors: an Introduction to Safe Use

New safer 'non-standardised' small bore (non-Luer) connectors are now being introduced across the NHS to minimise the risk of wrong route errors when administrating medication via oral/enteral and neuraxial routes.

These new connectors prevent the risk of mistakenly connecting the wrong devices and harm being caused when medication is delivered to a patient via the wrong route. For example, as they both used the same type of Luer connector, incidents have occurred where a device intended for intravenous medication had been mistakenly connected to a device that delivered the medicine intrathecally.

The introduction of the new safer connectors will help minimize the risk of cross connections of devices intended for different clinical applications by making connections to the different devices incompatible. It will also harmonize the UK's ISO connectors with those used in other countries.

To prevent further risks to patient safety, these new ISO connector designs must be introduced to the NHS in a co-ordinated manner. Risks may arise from healthcare organisations, professionals, patients and carers not being fully aware of the connector design change, and implication on clinical use. New risks include the supply and attempted use of incompatible devices and ancillary products, incorrect use of the new connectors and device shortages [14].

Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks: August 2017. Patient safety incidents are occurring due to the accidental administration of medication intended for intravenous use via a neuraxial device, and vice versa, resulting in the patient receiving

drugs through the wrong delivery route, which in some cases has been fatal.

To prevent these errors a new dedicated connector for neuraxial and regional block devices – NRFitTM (ISO 80369-6:2016) has been developed and is now being introduced to the NHS. Devices with this connector are not compatible with Luer connectors, preventing the risk of drugs being delivered through the wrong route. Industry has now adopted this new ISO standard for use throughout the UK and NRFitTM is now the dedicated connector for neuraxial devices. The Surety® devices introduced as an interim safety measure while the new ISO standard was being developed will now be discontinued. This alert supports providers with the safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks [15].

Florence Nightingale

'It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm' (Florence Nightingale, 1859) [16]. The concept that Florence Nightingale expounded cannot have been new even in her day, yet injury and death continue to occur as a result of medical error. Recent figures from the USA suggest that medical errors result in 1,000,000 excess injuries each year [17]. The Department of Health estimates the figure in the UK to be 850,000 a year despite a smaller population [18]. The cost of the resulting litigation to the National Health Service (NHS) may be as high as £400 million annually, a figure which continues to rise [18,19].

Inadvertent Epidural Injection of Drugs for Intravenous Use

The frequency of inadvertent injection of drugs in the epidural space is probably underestimated and underreported, but it can cause serious morbidity and possibly mortality.

The aim of this review is to collate reported incidents of this type, to describe the potential mechanisms of occurrence and to identify possible therapeutic solutions. We searched into medical databases and reviewed reference lists of papers retrieved. A list is reported of more than 50 drugs that were inadvertently injected into the epidural space. This list includes drugs which produce no, little or short-lasting neurological deficits, but also includes drugs that may be more etching and can result in temporary or even permanent neurological deficit.

Most drugs do not lead to sequelae other than pain during injection or transient neurological complaints. Other drugs may have more deleterious consequences, such as paraplegia. Both the dose of the inadvertent injected drug and the time frame play an important role in the patient's outcome. "Syringe swap", "ampoule error", and epidural/intravenous line confusion due to inaccurate or absent colour coding of epidural catheters were the main sources of error. Preventive strategies, including non Luer-lock epidural injection ports, might increase safety [20].

Avoiding Inadvertent Epidural Injection of Drugs Intended for Non-epidural Use

Inadvertent administration of non-epidural medications into the epidural space has the potential for serious morbidity and mortality. The aim of this study was to collate reported incidents of this type, describe the potential mechanisms of occurrence and identify possible solutions. We searched medical databases and reviewed reference lists of papers retrieved, covering a period of 35 years, regarding this type of medication incident. The 31 reports of 37 cases found is likely to represent a gross underestimation of the actual number of incidents that occur. "Syringe swap", "ampoule error", and epidural/intravenous line confusion were the main sources of error in 36/37 cases (97%). Given that no effective treatment for such errors has been identified, prevention should be the main defence strategy. Despite all the precautions that are currently undertaken, accidents will inevitably occur. We have identified areas for system wide change that may prevent these types of incidents from occurring in future [21].

Grand Mal Convulsion after an Accidental Intravenous Injection of Ropivacaine

A 36-yr old, ASA physical status I patient scheduled for hip arthroplasty under regional anesthesia received at the end of surgery an i.v. injection of approximately 200 mL of a 0.15% ropivacaine solution (300mg=4.6mg/kg) in approximately 5 min.

The bag prepared for postoperative epidural infusion was accidentally connected to a peripheral i.v. line. The patient developed grand mal convulsions, hypotension, and respiratory arrest. No arrhythmias were observed. Twenty minutes after the event, the arterial plasma concentration of ropivacaine was 3.10 microg/mL. Using a pharmacokinetic model, the peak plasma concentration at the time of the accidental administration was estimated at 17.04 microg/mL. The patient recovered uneventfully [22].

Woolley and Roe case

On October 13, 1947, two incidents occurred which resulted in one of the most famous of all medicolegal actions as far as the speciality of anesthesia was concerned. Two patients, Cecil Roe and Albert Woolley who were on the same operative list for relatively minor surgical procedures, developed permanent, painful, spastic paraparesis following spinal anesthesia with hypobaric 1:1500 cinchocaine (nupercaine; dibucaine) administered by the same anaesthetist. Both patients sued the hospital and the anaesthetist and the case came to court in October 1953 and lasted 11 days. This case had a profound effect on the practice of spinal anesthesia, as anaesthetists were fearful of producing permanent neurological damage and the technique, in the UK, was probably retarded by 20-25 years [23]. Noble and Murray in a review of 78,746 spinal anesthetics in Canada, found no permanent neurological sequelae [24]. Similarly, Moore and Bridenbaugh surveyed 12,386 and Dripps and Vandam-10,098 spinal anesthetics,

and did not find evidence of permanent neurological deficits. In an editorial published in 1975 on spinal anesthesia Scott and Thorburn wrote that "it has been virtually ignored in the last 20 years for several reasons, including the introduction of muscle relaxants [25-27]. Since the Woolley and Roe cases, reported in 1954, in which two patients developed painful and permanent paraplegia following spinal anaesthesia, the use of the technique in the United Kingdom has been confined to a few enthusiasts".

New studies on the history of anesthesiology (1)--A newly discovered truth on Woolley and Roe case after an interval of 50 years. A famous medical accident that is widely known as Woolley and Roe case occurred on Oct 13th, 1947 at the Chesterfield Royal Hospital, England. The patients Albert Woolley and Cecil Roe underwent minor operations under spinal anesthesia using cinchocaine to develop spinal cord myelopathy with paralysis of bilateral legs. Both patients sued Dr James M. Graham, the anesthetist, and the Ministry of Health. Seven years later, Dr Graham and the Ministry of Health were given a verdict of not guilty, because three judges unanimously accepted the phenol theory proposed by a witness Prof Macintosh of Oxford University. He alleged that phenol entered into the ampoule of cinchocaine through invisible cracks. Thus the plaintiffs were not compensated. Recentry Dr Hutter of Nottingham University found no validity of phenol theory and also no possibility of invisible cracks. Syringes and needles for spinal anesthesia were used to be sterilised by water-boiling steriliser, and mineral acid was used for descaling the deposition of line at that time. Dr Hutter concluded that the severe spinal myelopathy occurred both in Woolley and Roe would have been caused by mineral acid which was conveyed into their subarachnoidal space by acid-contaminated syringes and needles [28].

Conclusion

The story of the NRFit is like that written by William Shakespeare (bapt. 26 April 1564-23 April 1616)…

"To be, or not to be, that is the question: Whether 'tis nobler in the mind to suffer

The slings and arrows of outrageous fortune,

Or to take arms against a sea of troubles

And by opposing end them. To die—to sleep,

No more; and by a sleep to say we end

The heart-ache and the thousand natural shocks

That flesh is heir to: 'tis a consummation

Devoutly to be wish'd. To die, to sleep;

To sleep, perchance to dream—ay, there's the rub:

For in that sleep of death what dreams may come,

When we have shuffled off this mortal coil,

Must give us pause—there's the respect

That makes calamity of so long life.

For who would bear the whips and scorns of time,

Th'oppressor's wrong, the proud man's contumely,

The pangs of dispriz'd love, the law's delay,

The insolence of office, and the spurns

That patient merit of th'unworthy takes,

When he himself might his quietus make

With a bare bodkin? Who would fardels bear,

To grunt and sweat under a weary life,

But that the dread of something after death,

The undiscovere'd country, from whose bourn

No traveller returns, puzzles the will,

And makes us rather bear those ills we have than fly to others that we know not of?

Thus conscience does make cowards of us all,

And thus the native hue of resolution

Is sicklied o'er with the pale cast of thought,

And enterprises of great pitch and moment

With this regard their currents turn awry

And lose the name of action".

(from Hamlet, spoken by Hamlet)

WHY?

Because you cannot treat this problem by changing it from LUER to NRFit… it is not even close to imagination. To those who did not even anesthetize a person in their life… It is very easy to give a bottle of KCL instead of Bupivacaine into the epidural catheter with the "fake device" of NRFit… the patient will become paraplegic!!! [28]. Fortunately, "He was given calcium gluconate and potassium chelating agent along with supportive measures. The patient recovered within 8h".

To those who are giving it on a regular basis in the UK (Anesthesiologists): "Beware the ides of March".

Caesar

Who is it in the press that calls on me?

I hear a tongue shriller than all the music

Cry "Caesar!" Speak, Caesar is turn'd to hear.

Soothsayer

Beware the ides of March.

Caesar

What man is that?

Brutus

A soothsayer bids you beware the ides of March.

(Julius Caesar Act 1, scene 2, 15–19)

My humble Advice to the UK anesthesiologists: Throw the NRFit to the junk of anesthesia trash…and create a

new Rule by Anesthesiologists: Every epidural infusion or intravenous infusion should be inspected and signed by 2 medical professionals- doctor or nurse (like it is the rule worldwide for giving blood and blood components).

References

1. Nick Triggle (2018) Drug errors cause appalling harm and deaths, says Hunt.
2. Neuraxial-Specific, 80369-6.
3. Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirements, ISO 594-1:1986.
4. HSC 2008/001: Updated national guidance on the safe administration of intrathecal chemotherapy (2008) Department of Health (England).
5. Hew CM, Cyna AM, Simmons SW (2003) Avoiding inadvertent epidural injection of drugs intended for non-epidural use. Anaesth Intensive Care 31: 44-49.
6. Institute for Safe Medication Practices-Canada, Safety Bulletin (2001) Published data supports dispensing vincristine in minibags as a system safeguard.
7. National Patient Safety Agency (2007) Patient Safety Alert 21. Safer Practice with Epidural Injections and Infusions.
8. Drake JM, Crawford MW (2005) Near-miss injection of an anesthetic agent into a cerebrospinal fluid external ventricular drain: special report. Neurosurgery 56: E1161.
9. New South Wales Health (2006) Safety Alert 04/06. Safe Use of vincristine.
10. The Joint Commission (USA)/Sentinel Event Alert. Preventing vincristine administration errors.
11. The Telegraph (2008) Cancer patient dies after wrong injection. Calcutta, India.
12. Food and Drug Administration (2009) Look, Check and Connect. Safe medical device connections save lives. Medical Devices Calendar.
13. Small bore connectors: an introduction to safe use (2017) NHS Improvement.
14. National Patient Safety Alerts (2018) Safe anaesthesia Liaison Group.
15. Thomas CGA (1988) Medical Microbiology. London: Bailliere Tindall.
16. Kohn LT, Corrigan JM, Donaldson MS (1999) To Err Is Human. Building a Safer Health System. Washington, DC: National Academy Press.
17. Department of Health (2000) An Organisation with a Memory-Report of an Expert Group on Learning from Adverse Events in the NHS. London: HMSO.
18. Fenn P, Diacon S, Gray A, Hodges R, Rickman N (2000) Current cost of medical negligence in NHS hospitals: analysis of claims database. British Medical Journal 320: 1567-1571.
19. Beckers A, Verelst P, van Zundert A (2012) In advertent epidural injection of drugs for intravenous use. A review. Acta Anaesthesiol Belg 63: 75-79.
20. Hew CM, Cyna AM, Simmons SW (2003) Avoiding inadvertent epidural injection of drugs intended for non-epidural use. Anaesth Intensive Care 31: 44-49.
21. Dernedde M, Furlan D, Verbesselt R, Gepts E, Boogaerts JG (2004) Grand mal convulsion after an accidental intravenous injection of ropivacaine. Anesth Analg 98: 521-523.
22. Morgan M (1995) The Woolley and Roe case. Anaesthesia 50: 162-173.
23. Noble AB, Murray JJ (1971) A review of the complications of spinal anaesthesia with experience in Canadian teaching hospitals from 1959-1969. Can Anaesth Soc J 18: 5-17.
24. Moore DC, Bridenbaugh LD, Bagdi PA, Bridenbaugh PO, Stander H (1968). The present status of spinal (subarachnoid) and epidural (peridural) block: a comparison of the two technics. Anesthesia & Analgesia 47: 40-49.
25. Dripps RD, Vandam LD (1954) Long term follow-up of patients who received 10,098 spinal anesthetics. JAMA 156: 1486-1491.
26. Scott DB, Thorburn JT (1975) Spinal anaesthesia. Br J Anaesth 47: 421-422.
27. Matsuki A (2000) New studies on the history of anesthesiology (1)--A newly discovered truth on Woolley and Roe case after an interval of 50 years. Masui 49: 686-692.
28. Rahul Ranjan, Naiyer Asif, Sohail Ahmad, Syed Ifthekar (2016) Inadvertent injection of potassium chloride instead of sodium chloride during treatment of chronic low back ache with epidural injection leading to paraplegia. J Craniovertebr Junction Spine 7: 279-281.