Title : A Non-Interchangeable Connector for Central Venous Pressure Lines

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Abstract

The unintentional peripheral administration of other irritant and vasoconstrictor drugs or parenteral nutrition solutions is common. It causes phlebitis and tissue necrosis and may even be fatal. The prevention of the incorrect connection of infusions intended for central venous administration requires an engineered solution. The introduction of unique connectors that prevent misconnection of neuraxial and gastric feeding lines do not and cannot address this problem as there is an absolute requirement to be able to connect a standard luer syringe to the central line. All peripheral infusions and injections can safely be given into a central catheter, however, the central line infusion set should not be able to connect with a standard female luer.
The NHS has identified the incorrect administration of concentrated potassium solutions as a “Never Event.” Despite rigorous checking procedures and multiple systems solutions, these errors continue to occur. This error occurs because there is no engineered solution preventing the misconnection of a drug intended for central delivery to a peripheral cannula. The luer connection is ubiquitous to all intra-venous devices whatever their route.

In 2006, JCAHO issued an alert highlighting the dangers of tubing misconnections. Similar problems have been identified in the NHS and other health services across Europe. Inadvertent connections of infusions intended for the central venous catheter (CVC) to the peripheral cannula (PC) are possible because both carry identical luer connectors. This error risks both thrombo-phlebitis and tissue necrosis which may be extensive, even requiring surgery.

Unlike other routes (nasogastric and neuraxial), it is not possible to introduce a totally unique connector for central systems as there is a requirement for the central system to accept standard luer infusion sets and luer syringes. This is necessary to enable the administration of emergency drugs in a timely way and to allow the central administration of those non-irritant drugs which can be given both centrally and peripherally. All drugs that can be delivered peripherally are safe for administration into CVC.

We present a risk-free, seamless solution to this problem – the Non-Interchangeable Connector System. Two modifications are required. Firstly, the CV catheter female luer connector would be altered in such a way that it would accept both the conventional luer syringes and infusion lines (see figure 1) and also a new male non-interchangeable connector (NICS) on lines that are intended only for central delivery (see figure 2). The male NICS located on a CV infusion line would not connect to the luer connector on a PC.
The NICS CVC has a NICS female connector with 4 projections, each with a circumferential dimension equal to that on the lip of the standard luer connectors. This allows it to connect to both standard luer and NICS infusion lines and syringes. The NICS CV infusion line has a male NICS connector with a corresponding disc with a key structure allowing the engagement of the 4 projections of the NICS CV catheter but this disc would prevent engagement with the standard female luer connector on a peripheral cannula.

The female NICS connector on the CV catheter still allows access with standard syringes/infusion lines allowing seamless and safe introduction of the NICS system.

We have carried out a study of the use of the prototype NICS in our hospital aiming to prove that the NICS would prevent central to peripheral misconnection and that it allows the connection of standard luer infusions and syringes to the CVC.

The primary outcome measure was the ability to connect NICS infusion to NIC CVC but not to a PC and the ability to connect standard luer infusion to both PC and NIC CVC.

We also used a visual analogue scale (VAS) and measured the time taken for connection of NIC-NIC versus standard luer – PC.

Methods:

Clinicians (n=66) were timed making NIC and standard luer connections and were asked to complete a questionnaire with a visual analogue scale (VAS) for ease of use of the standard luer and NICS connectors.

Results:

Connection success results are presented in table 1. All connections were possible except no-one was able to connect the male NICS to a female luer.

The mean VAS for the luer connector was 0.34cm of 10cm compared with 1.13cm of 10cm for the
The mean time to connect the luer-lock was 1.22 seconds compared with 1.7 seconds for the NICS. Whilst statistically significant, this difference is clinically irrelevant.

<table>
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<th>NIC Female Connector (NIC CV catheter connector)</th>
<th>Standard Luer female connector (PC connector)</th>
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<tbody>
<tr>
<td>NIC Male Connector (NIC CV infusion set)</td>
<td>66 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Standard Luer Male connector (Standard infusion or syringe)</td>
<td>66 (100%)</td>
<td>66 (100%)</td>
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Table 1: Ability to connect NICS and Luer connectors

Conclusions

Errors in the route of administration of irritant and vasoconstrictor drugs continue to cause avoidable patient injury in hospital practice. Total parenteral nutrition is frequently given in the ward environment and must not be connected to anything but a central venous line. These patients commonly have both a CV catheter and a peripheral catheter in place and so errors can and do occur. A typical critically ill patient has a multiple lumen central venous cannula, a number of peripheral venous cannulae, an arterial line and a spinal or epidural catheter all with the associated 3-way luer connectors. Commonly, any one patient can have over 10 luer lock connections around their bedspace allowing access to many different routes. It is essential that drugs intended for central line administration should not be able to be connected to any other luer connector and it is also equally important that standard luer (male) connector infusions and syringes should continue to fit on an CV catheter. Due to the nature of general hospital and critical care interventions lines are frequently disconnected, replaced or swapped. An unfortunately common error is to connect a line containing fluid that can only be given safely through a central vein (e.g. concentrated
potassium chloride, TPN or vasoconstrictors) to a peripheral cannula resulting in phlebitis or necrosis. This is painful and distressing for the patient and often leads to disciplinary action against staff and may be fatal.

Safety considerations

It is important when introducing new systems that are intended to prevent rare complications into a healthcare environment that an additional risk is not introduced. Simple calculations indicate that there are many thousands or millions of luer connector interactions for each episode of significant patient harm associated with CV infusion misconnection. Any system must therefore introduce zero risk to each of these normal connections. Ideally the teaching of staff should be minimal and they would not need any understanding of the system. A previous study of 52 intensive care nurses surveyed following the introduction of the NIC air connector (a non-indexed NIC) into clinical practice showed that although routinely using NICS, none were aware of a change and only became aware once they were asked to attempt a misconnection [MDT Evans].

There are several market drivers for the introduction of a NIC system. In addition to the patient safety benefits, these would potentially benefit both pharmaceutical companies as well as CVC manufacturers

Firstly, by providing concentrated potassium solutions, TPN and vasoconstrictor agents in an infusion system which ends in the NIC, the drug companies would be able to prevent the misadministration of these drugs into peripheral cannulae. This would allow drug manufacturers to distribute their drug as a safer alternative to other generic drugs. The NHS Never Event would truly become a never event as it would now be impossible to misconnect the concentrated potassium solution to a peripheral cannula.
There would also be commercial viability for the manufacturers of CVC and peripherally inserted CVC lines. It would be possible to introduce the new safe NIC CVC without any need for retraining or even letting clinicians know that there had been an alteration, however they could be marketed as a safer system.

In conclusion, engineered solutions to infusion misconnection problems are needed. No additional risk should be introduced with any new system. The NICS offers such a solution. Our studies have demonstrated the system would be effective at preventing these tragic errors.
Figure 1a and 1b – Components of the NICS Central Drug Infusion Line (patent pending)
Figure 3
References

1. NHS Never events
2. Never Event report 2009-2010
3. JCAHO – Sentinel Alert
5. M. Evans et al