New international design standards for medical device connectors are being rolled out globally to prevent life-threatening misconnections

Enhancing patient safety in enteral feeding

In this article...

- The problems with enteral feeding connections
- Solving the problem on a global scale
- Introduction of the new ENFit connector system

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Abstract

Healthcare is littered with aphorisms and clichés, one of the best-known being “first, do no harm”. Unfortunately, in any clinical setting it is a fact that “accidents will happen”. When they do, it is the duty of all professionals to do what they can to ensure they do not recur.

The potential for incorrect connection of fluid lines, catheters and syringes has long been recognised. While misconnections are rare, where they occur they can be damaging – even life-threatening (Guenter et al, 2009; Eakle et al, 2005). They may arise due to confusion about a new patient’s medical history or during the transfer of a patient between departments. They may also occur in treatment situations that require multiple tasks to be performed simultaneously and speedily; such situations require action at the level of individual hospitals and professionals (Simmons et al, 2009; 2008).

The universal design of the Luer connector make it possible for inadvertent connection of an enteral feeding device (such as an enteral feeding-giving set) and an intravenous line to occur, since this means that enteral feed could fatally be administered into a patient’s blood – device design changes are clearly needed (Guenter et al, 2009). This requires cooperation between health professionals and the medical device industry.

Such cooperation in the UK led to the development of the “reverse Luer” (purple) system, which was introduced in 2007 after the issue of the National Patient Safety Association’s Alert 19 (NPSA, 2007). This dramatically reduced the risk but addressing the problem in one country when usage is global, left a gap that needed filling.

Addressing the problem globally

To improve patient safety – and partly as a result of the work carried out in the UK around the aforementioned reverse Luer (purple) system in 2007 – new international design standards for medical device connectors are being rolled out globally.

In 2011, an International Standard (ISO 80369-1) was established setting general requirements for small-bore connectors for liquids and gases; these made it difficult (if not impossible) for unrelated delivery systems (such as enteral feeding devices and IV lines) to be connected. Subsequently, new nutrition ports and administration set connectors are being introduced across all enteral nutrition devices to meet the new design standards. These devices comprise:

- Enteral giving sets;
- Enteral syringes;
- Nasogastric feeding tubes;
- Naso-jejunal feeding tubes;
- Percutaneous endoscopic gastrostomy (PEG) tubes;
- Gastronomy tubes (G-tubes);

Key points

1 The risk of misconnecting enteral feeding tubes to intravenous devices was well known
2 Connection errors can be fatal
3 The reverse Luer (purple) system, introduced in the UK in 2007, dramatically cut the risk of misconnecting tubes
4 ENFit was developed to address the misconnection problem globally
5 ENFit transition sets will be introduced in the UK from September 2015
Button gastrostomies; Jejunostomy tubes.

In practice, this will mean all enteral devices will have the same connection system. As such, an enteral device can only connect to another enteral device – it cannot connect to an IV device. The collective name for the new global connector is ENFit.

Introducing ENFit in the UK

Before the International Standard came into force, manufacturers in the UK and Republic of Ireland worked with the NPSA on introducing the reverse Luer (purple) system. This followed a review of data from the NHS Reporting and Learning System in 2007, which showed there were 33 patient safety incidents involving IV administration of oral liquid medicines between 1 January 2005 and 31 May 2006. As a result, healthcare organisations, such as NHS trusts, were advised to review:

- The design and supply of the oral/enteral syringes and enteral feeding systems being used;
- How they were used.

They were also advised to review and amend best-practice procedures, training and audit where necessary (NPSA, 2007).

Today, the UK has an excellent safety record in enteral feeding practice. Nevertheless, given that it is still possible to obtain an adapter that will change a reverse Luer (purple) back into a standard Luer, and with increasing numbers of patients travelling internationally, a single global solution is required to ensure patient safety and prevent possible misconnection or no connection of enteral feeding tubes, giving sets and syringes to IV devices.

ENFit will replace the reverse Luer (purple) connector systems in the UK to ensure there is one global enteral connector. It will look very similar to the existing connector, but with a slightly larger bore size. In the UK, the Enteral Plastic Safety Group (EPSG) has been set up to help manage the introduction of ENFit. It comprises the main enteral device companies and NHS stakeholder groups, such as the National Nurses Nutrition Group (NNGC), that are involved with the production, sale and use of enteral tube feeding devices. The switch to ENFit will begin with transition enteral feeding-giving sets and enteral feeding gravity sets being introduced from September 2015.

These transition sets will feature the new ENFit connector but will also be supplied with adapters to enable connection to non-ENFit enteral feeding devices. All other ENFit enteral feeding devices, such as nasogastric feeding tubes and gastrostomy tubes, will be available from March 2016.

This two-phase approach will ensure use of existing manufacturers’ enteral-giving set stock, as well as making sure the enteral giving sets used by all patients (be they in hospital or the community) feature ENFit before the ENFit enteral feeding devices are introduced.

How will this affect nurses?

In practice, the new design standard will affect all enteral feeding tubes (nasogastric feeding tubes, naso-jejunal feeding tubes, PEG tubes, G-tubes, button gastrostomy tubes and jejunostomy tubes), enteral syringes, pump-giving sets and enteral gravity sets. At the nutrition end (that is, where the enteral giving set is connected to the bag or bottle of enteral feed), a safe connection system called ENPlus is already in place – this will not be changed.

As mentioned, from September 2015 all enteral giving sets and gravity sets will be supplied with ENFit transition connectors that allow compatibility between the patient’s existing feeding tube port and the new ENFit giving set. The transition sets will be in circulation for approximately 12 months. This will ensure connectivity between old and new enteral feeding tubes in patients who are fed via tube until all enteral-giving sets and enteral feeding tubes feature the new ENFit connection.

ENFit enteral feeding tubes and syringes will be introduced in March 2016. Features will be as follows:

- Patient-access end syringe – the new connector requires a new ENFit syringe that can be used for medicines, flushing, hydration or bolus feeds. Current reverse Luer-tipped syringes will not fit the new ENFit connector.
- Transition sets will be used to facilitate connection to existing reverse Luer feeding tubes until new tubes with ENFit are introduced;
- Patient-access end feeding tube – new tube with the ENFit connector. Feeding tubes will change from the reverse Luer connector to the new ENFit connector.

It is envisaged that the new ENFit connector will be rolled out across all enteral feeding devices over 12 months, after which transition sets will be removed from use. Manufacturers will work closely with customers to ensure the transition process has minimal impact on patient care.

Further information

A growing platform of information is now available to support the introduction of ENFit. Globally, the introduction is being managed by the non-profit Global Enteral Device Supplier Association. GEDSA is being supported in the UK by the EPSG, which represents all leading UK enteral feeding device suppliers and, in turn, is supported by clinical and patient representation from the Parenteral and Enteral Nutrition Group of the British Dietetic Association, NNG, BAPEN, British Pharmaceutical Nutrition Group and Patients on Intravenous and Nasogastric Nutrition Therapy, as well as NHS England.

Your enteral feed/enteral feeding device supplier will be your first port of call for information and support. In addition, the EPSG is providing a full range of communications, from conference attendance to advertising and direct mail/email to help ensure UK health professionals are fully aware of the change and prepared for the introduction of ENFit. Further information is also available via GEDSA’s dedicated website: www.stayconnected.org.

Conclusion

To address the risk of inadvertently connecting an enteral feeding tube to an IV device, the reverse Luer (purple) system was developed for use in the UK. However, to tackle the problem globally and reduce the risk of life-threatening errors occurring, the ENFit connector was designed. This will be introduced in the UK in a phased process, which will begin with the introduction of transition sets in September 2015. Health professionals should ensure they are aware of the new system and are adequately trained in how to use it.