Learning the Lesson of Using the Right Administration Route

The final chapter in the ENFit story nears completion

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In January 2001, 18-year-old Wayne Jowett was due to receive chemotherapy with intravenous vincristine and intrathecal methotrexate to maintain his leukaemia in remission. Tragically, vincristine, a potent cytotoxic drug that should not be administered using the intrathecal route, was mistakenly injected into his spine. Despite emergency treatment, Wayne died about a month later. The external enquiry into the death made several recommendations, including redesigning the connection for spinal needles so that they cannot fit the Luer mounts on intravenous syringes.[1]

Increasing concerns that misconnections between devices when administering drugs could lead to potentially serious adverse events prompted a major revision of the standards covering connectors for a wide range of clinical applications. For example, ENFit is a global patient safety standard that means that all enteral plastics will use the same connection system: an enteral plastics device will only connect to another enteral device and not to an intravenous device. For example, a reverse Luer-tipped syringe will not fit the new ENFit male connector tube.

The NHS led a collaboration with feed and device companies involved in medical nutrition and began implementing the switch to ENFit in 2015. As the two-phase implementation process approaches completion, all healthcare professionals involved in medical nutrition need to be aware of the implications of the switch to ENFit. This article describes the background to this change, which improves safety for every patient receiving enteral feeds.

Growing concerns – confusion of administration routes

The tragic case of Wayne Jowett highlighted increasing concerns about misconnections of Luer tubes, for example:

- A Health Service Circular noted that intrathecal vincristine had caused paralysis or death in at least 55 cancer patients worldwide[2]
- The National Reporting and Learning System received 33 patient safety incidents involving intravenous administration of oral liquid medicines between 1 January 2005 and 31 May 2006. Indeed, incorrect intravenous administration of oral liquid medicines resulted in three deaths between 2001 and 2004, and four incidents of harm or near misses between 1997 and 2004[3]
- The National Standards Authority of Ireland noted the growing concern about deaths or injuries arising from the misconnection of particular devices, or the inappropriate delivery of compressed gases, enteral solutions and parenteral feeds.[4]

Against this background, the National Patient Safety Agency (NPSA) stated that **enteral feeding systems should not contain ports that could be connected to either intravenous syringes or to intravenous or other parenteral lines.** The NPSA advocated that enteral feeding tubes should use a female Luer connector to fit male ports – the so-called reverse Luer connection.[3] In addition, enteral syringes and associated equipment was coded purple to distinguish these products from intravenous syringes, which are coded yellow.[5] The reverse Luer system reduced the risks associated from misconnections in the UK. Occasionally, however, the reverse Luer system allowed misconnections with small-bore tubes, including those used in enteral feeding.

Protecting patients worldwide

Stakeholders, including clinicians, and governmental and professional organisations, recognised the importance of protecting patients worldwide. Therefore, in 2008, a working group of the International Organisation for Standardisation (ISO) began developing standards for alternative connectors for enteral and respiratory applications (ISO 80369). The first part of the standard, published in 2010, covers small bore connectors for, among other routes, epidural, intravenous and enteral access. The third part (ISO 80369/3), published in 2016, established standards for connectors used in enteral feeding.

While the ISO deliberated, feed and device companies involved in medical nutrition established the Enteral Plastics Safety Group (EPSG), in 2008, to improve safety in patients receiving enteral feeds. For example, the EPSG ensured uniformity and alignment of terminology, and manufacturer and practice guidelines, which helps avoid confusion and ensure consistent and equitable practice.

The EPSG developed standardised compliance with best practise by engaging with a wide range of stakeholders, including senior clinicians, the British Association for Parenteral and Enteral Nutrition (BAPEN), the British Dietetic Association (BDA) and

the National Nurses Nutrition Group (NNNG). The EPSG also collaborated with regulatory and statutory bodies, such as the British Standards Institution (BSI), the Medicines and Healthcare products Regulatory Agency (MHRA), the NHS Supply Chain (NHSSC), the National Institute for the Health and Care Excellence (NICE) and the NPSA.

Based on these discussions, ENFit emerged as the preferred patient safety standard globally to meet ISO 80369/3. The ENFit patient safety standard means that all enteral plastics will have the same connection system. An ENFit enteral plastics device will only connect to another enteral device and not to an intravenous device. Feeding tubes look similar to the older products, although the bore is slightly larger.

Implementing ENFit

As with the introduction of the reverse Luer system, the NHS is among the world leaders and has adopted the ENFit patient safety standard in a two-phase implementation plan. A wide range of products now meet the ENFit standard, including button gastrostomy, percutaneous endoscopic gastrostomy, nasojejunal and nasogastric tubes, syringes, extension and giving sets, as well as the bottle adaptors (bungs) and filter straws (quills) that help draw liquid medicines into ENFit syringes. In addition, manufacturers developed adaptors that connect ENFit syringes and giving sets to existing gastrostomy tubes to avoid the need for surgical replacement.[5]

The EPSG developed the two-phase implementation plan in consultation with NHS England, NHSSC and the Parenteral and Enteral Nutrition Group of the BDA and began promoting the change to ENFit at the BAPEN conference in October 2014 in Harrogate. Individual companies launched communication plans to facilitate and encourage implementation of the ENFit standard locally. The NHS England Small Bore Connectors Advisory Group, which oversees NHS implementation, first met in July 2014.

During 2015, however, concerns arose regarding the accuracy of low-dose syringes using ENFit connectors, which delayed implementation. Syringes of 5 ml and above have a hub at the connection to ENFit giving sets, which holds about 0.2 ml. Bottle adaptors and filter straws can clear the hub before administration, therefore, lead to under-dosing. On the other hand, if the hub is full before oral administration and the patient sucks on the syringe they may receive a 0.2 ml overdose of a liquid medication. A 0.2 ml difference for a volume greater than 2.5 ml is unlikely to be clinically significant. Nevertheless, healthcare professionals should use the same products and techniques to ensure dose consistency.[5]

Concerns over accuracy are potentially more serious with low-dose syringes (2.5 ml and below). The tip of the syringe can include a dead space (known as the moat) of up to 0.025 ml, which represents a 25% error on a volume of 0.1 ml.[5] Although a small absolute volume, the overdose could be clinically significant when administering, for example, morphine, digoxin and methadone to paediatric patients. As a result, the EPSG adjusted the timeline to investigate concerns about the accuracy of very low dose syringes.

Addressing concerns

In response to these concerns, the ENFit Low Dose Tip (LDT) improves accuracy when administering small volumes of medications. The LDT consists of a standard female ENFit connector syringe tip with an internal male lumen. This allows the LDT to have the same functionality as a traditional male enteral or oral syringe as well as a geometry and configuration that are similar to Luer locks.[6]

A study by the Surgical Materials Testing Laboratory in South Wales found no statistically significant difference in dose volume between the ENFit LDT and the male Luer lock syringe. The authors concluded that: *"The ENFit Low Dose Tip provides a solution for accurate enteral dosing of low volumes while maintaining compatibility with the ENFit connector system."*[6]

LDT syringes, supported by specific instructions for use, began to reach the market in July 2016. Therefore, healthcare professionals need to ensure that they use the correct syringe. Any dose of liquid medication greater than 2.6 ml should be administered using the syringe that is closest in size: a 3 ml ENFit Standard Tip Syringes for a 2.6 ml volume, for instance. Any volume of 2.5 ml or less should use the LDT. Moreover, using a bottle adaptor or filter straw can avoid medication around the moat of the LDT or in the tip of the ENFit Standard Tip Syringe.

When using ENFit products, healthcare professionals should remember that only a quarter turn is needed to make connections using ENFit Standard Tip Syringes. In addition, flushing the inside threads of the tubes helps avoid disconnection problems and keeps the device clean. Feed and device companies offer training on the use of the new products. Local protocols should also summarise the correct procedures.

Towards final implementation

The ENFit products now available allow full implementation of the patient safety standard envisaged in ISO 80369/3. Local NHS organisations should have developed an implementation plan in collaboration with their local feed and device contractors, within local procurement guidelines. To ease implementation, transition giving sets remained available until January 2017, after which they were discontinued. However, loose adapters will remain available until all devices are ENFit compliant. In other words, the first phase of the implementation plan is now complete with most patients using ENFit giving sets.

The availability of the syringes means that the second phase of the implementation plan is nearing completion. Over the past 12 months, the EPSG and individual companies have been working with Trusts and healthcare professionals to provide education on ENFit devices and encouraging Trusts to solely use ENFit. In the future, products that do not meet the ENFit patient safety standards will be discontinued, although the exact date when this will occur is not yet clear.

More than a decade after the ISO began developing standards for alternative connectors for enteral and respiratory applications, we are rapidly approaching full implementation of ENFit in the UK. Patient safety was the focus of all stakeholders throughout the process. The change to the ENFit standard represents an important advance in patient safety – and the NHS has been among those leading the way globally.

Further information

For ongoing support contract your device and feed provider for further information about the transition to ENFit. In addition, the following websites may be useful:

- National Nurses Nutrition Group: www.nnng.org.uk
- NHS Improvement on small bore connectors: https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction
- Parenteral and Enteral Nutrition Group: www.peng.org.uk
- Stay Connected: http://stayconnected.org

References: **1.** Toft B (2001). External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham. Accessed online: https://webarchive.nationalarchives.gov.uk/20040209163606/ http://www.doh.gov.uk:80/qmcinquiry/ (Mar 2019). **2.** Department of Health Health Service Circular (2008). Updated national guidance on the safe administration of intrathecal chemotherapy. Accessed online: https://webarchive.nationalarchives.gov.uk/20130104175622/ http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_086870 (Mar 2019). **3.** National Patient Safety Agency (2007). Promoting safer measurement and administration of liquid medicines via oral and other enteral routes. Accessed online: www.sps.nhs.uk/wp-content/uploads/2018/02/2007-NRLS-0408-Liquid-medicines-PSA-2007-03-28-v1.pdf (Mar 2019). **4.** National Standards Authority of Ireland (200). Luer Connectors - A Report To CEN Chef From The CEN Forum Task Group "Luer Fittings". Accessed online: https://infostore.saiglobal.com/preview/98693689607.pdf?sku=881770_SAIG_NSAI_NSAI_ 2094557 (Mar 2019). **5.** Neonatal and Paediatric Pharmacists Group (2016). Update on ENFit Syringes. Accessed online: www.sps.nhs.uk/wp-content/uploads/2017/04/NPPG-Update-On-ENFit.pdf (Mar 2019). **6.** Deken A, et al. (2016). Dose Accuracy – Performance Testing of Enteral, Oral, ENFit®, and ENFit LDT Syringes. Accessed online: http://stayconnected.org/wp-content/uploads/2016/10/GEDSA-ENFit-LDT-Research-Poster.pdf (Mar 2019).