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ENFit Enteral Nutrition Connectors: Benefits and Challenges

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Abstract

New enteral connectors are now available based on the development of standards using the International Organization of Standardization process to prevent misconnections between systems that should not connect. Enteral devices with the new patient access connectors, called ENFit, are being now introduced for the purpose of improving patient safety. Transitioning to these new connectors poses benefits and challenges for facilities or agencies implementing these new devices. Information from appropriate resources should be sought by clinicians who need to partner with their suppliers and clinical organizations to see how best to meet these challenges. (*Nutr Clin Pract*.XXXX;xx:xx-xx)

Keywords

enteral nutrition; feeding tubes; connectors; safety; nutrition support

In 1972, the first report of accidental infusion of enteral nutrition (EN) into an intravenous (IV) line was published, and since then, clinicians have been concerned about misconnections.[1] An enteral misconnection is defined as an inadvertent connection between an enteral feeding system and a nonenteral system such as an intravascular line, peritoneal dialysis catheter, tracheostomy tube cuff, medical gas tubing, and other medical devices. In many reports, serious and even fatal patient harm occurred when nutrition formulas or medications, intended for administration into the gastrointestinal (GI) tract, were administered via the wrong route.[2]

A small-bore connector is a connector with an inner diameter of <8.5 mm that is used to link or join medical devices for the purpose of delivering fluids or gases. The luer connector is a classic small-bore connector commonly used in the healthcare setting as a universal connector. The use of the luer connectors on medical devices has contributed to misconnections between many types of therapeutic applications. Misconnections continue in many healthcare settings despite education and cautions from regulatory and safety agencies.

Incidence of Enteral Misconnections

More than 116 reported cases of enteral misconnections were reported in 1 large review, spanning 1972–2010.[3] The severity of this type of error was high and resulted in the death of the patient in 18% of the reports due to ensuing embolus or sepsis. Like other voluntary adverse event reporting systems, enteral misconnections may be greatly underreported. Despite the 2006 sentinel alert, enteral misconnections continue to be reported in the literature.[3,4]

In 2006, The Joint Commission (TJC) issued a sentinel event alert regarding tubing misconnections, which called for design changes in small-bore connectors.[5] TJC urged manufacturers to implement "incompatibility by design" features and stated that "forcing function" design changes would help make incorrect connections impossible. They also stated that a physical barrier is the most effective preventive tool when inappropriate connections are attempted, and the entire line of connections must be unique to prevent mistakes in connection.[5]

Actions to Prevent Misconnections

The International Organization of Standardization (ISO) convened a working group in 2008 to develop standards for the redesign of small-bore connectors. The first step was to develop a master standard for small-bore connectors that contained requirements for all small-bore connectors. This standard was published as ISO 80369-1 and is called *Small Bore Connectors for Liquids and Gases in Healthcare Applications—Part 1: General Requirements*.[6] The requirements for that connector standard included the following: (1) not connectable to others in the series, (2) made of rigid or semi-rigid material, (3) passing a misconnection test, and (4) not connectable with luer or

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needleless connector ports. This master standard is the basis for respiratory, enteral, noninvasive blood pressure monitoring, neuraxial, urology, and intravascular redesigned connectors.

The next step was to develop an enteral-specific connector standard deemed ISO 80369-3, which was approved worldwide in 2015 and published in July 2016.[7] This enteral connector, branded in the standard as ENFit, can be seen in Figure 1 and will be on enteral administration sets, enteral syringes, and enteral feeding tubes. Administration sets with these connectors were introduced into the U.S. market in spring 2015. A transition set was placed on the new administration sets and will continue to be available to ensure that patients receive their EN formula, hydration, and medications through the transition period. Figure 2 illustrates the transition set, which is a single-piece adapter. The new feeding tubes and enteral syringe with this connector are now on the U.S. market. Communication about these connectors can be found on Global Enteral Device Supply Association (GEDSA) website (www.StayConnected.org).[8] Facilities should also work with your individual device manufacturers to plan the transition.

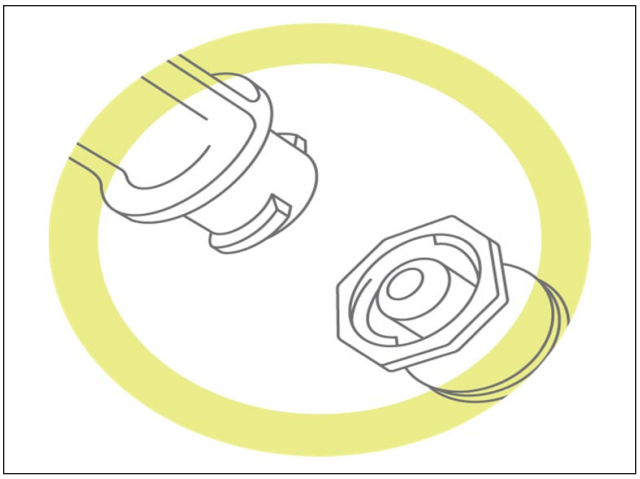

Figure 1. Patient access enteral connector. Reprinted with permission from the Global Enteral Device Supply Association (GEDSA).

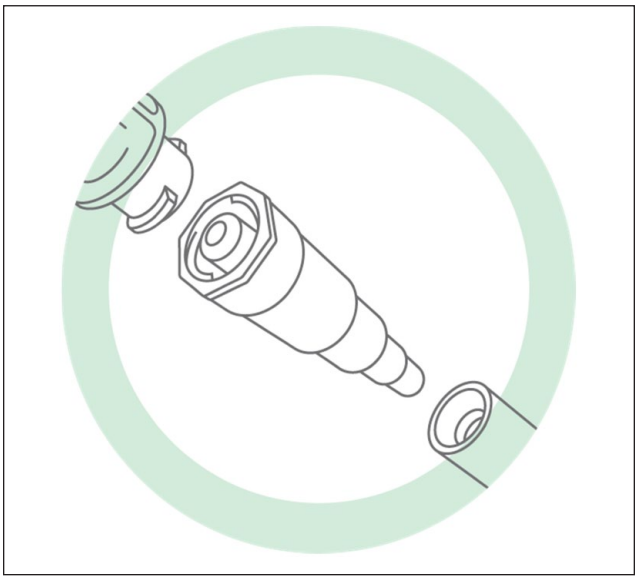

Figure 2. Patient access transition set. Reprinted with permission from the Global Enteral Device Supply Association (GEDSA).

Benefits of the New Enteral Connector: ENFit

ENFit, the new enteral connector, lends the enteral delivery system a safe, consistent connector for all devices. It is a screw-type connector, unlike the slip type of previous connectors. This prevents the connector from pulling apart and pumping formula into the patient's bedclothes instead of into the patient. Its harder plastic allows for leak prevention, and the most important feature prevents misconnections. This system protects 2 potential victims: the patient and the nurse or clinician (as the second victim) who makes the error. It is important to remind skeptical families and clinicians that this is a global effort to ensure safety.

Challenges With the New Enteral Connector: ENFit

Medication Administration

Challenges have emerged since the new ENFit connector was introduced. The first challenge is around the issue that the system has a reversed orientation to the previous enteral delivery system, that is, the tube has a male end and the administration sets and syringes have a female end. This female syringe configuration resulted in additional dead space, which clinicians communicated would be problematic with low-dose medication accuracy. This is especially important for medications with a low therapeutic index such as cardiac medications or narcotics and administered mostly to preterm infants and small children. Due .to this issue, a low-dose tip syringe was developed, tested, and approved by the U.S. Food and Drug Administration (FDA). This testing showed superb accuracy compared with regular-orientation medication syringes.[9] With the low-dose ENFit syringe, dead space was reduced to meet the dosing accuracy expectation of ±10% for a target volume of 0.2 mL.[9] Medications delivered via 1-mL and 3-mL (and, for some manufacturers, up to 6-mL) syringes will have the new low-dose tip. It is possible that some medication will accumulate in the moat or area outside of the male inner tip. If this is the case, gently flicking the end of the syringe can remove the excess medication. For more detailed information on the low-dose tip syringe, see the "Low Dose Tip Syringe Review."[9]

Some facilities will elect to use these new syringes for oral and enteral feeding tube administration to address space constraints associated with stocking both oral and ENFit syringes. If this is the case, care must be taken to allow for safe administration into the mouth of the child. Some manufacturers have devices that allow for such use. When this is done in a clinical setting with the expectation that parents will do the same at home, nursing staff should provide appropriate education and medication administration

Figure 3. Male end or port of an ENFit feeding tube. Reprinted with permission from the Medtronic, Inc.

supervision. A full step-by-step procedure for medication preparation and administration for inpatients can be found in the Supplementary Material (Procedure 1 available online at http://ncp.sagepub.com/supplemental).

Cleaning the Male End or Port of the Feeding Tube

Due to the reverse orientation of the new enteral delivery system, the end or ports on a feeding tube are now male (see Figure 3). Many questions have been posed about the risk of contamination with this connector configuration. Over time, there has been concern about bacterial contamination of enteral feeding delivery systems with documentation of retrograde bacterial movement of endogenous bacteria and biofilm development within the feeding tube. Studies have documented these phenomena in adult critically ill patients and neonates alike.[10,11] One study of adult patients looked at bacterial growth in enteral formula compared with the enteral delivery set tubing and found significant growth of *Enterobacter and Pseudomonas* species in the tubing but not formula. Investigators hypothesized these bacteria were endogenous in origin.[10] Another study of feeding tube composition found comparable and concerning significant bacterial growth of *Staphylococcus aureus* within polyurethane and silicone feeding tubes.[12]

Pediatric and neonatal feeding tubes and extension sets are either silicone or polyurethane. Residual enteral formula and medications could potentially accumulate in the male port of the feeding tube or extension set. This could serve as a nidus for bacterial growth, which could be particularly detrimental to neonates. One study documented outcomes related to bolus vs gravity drip feeding of 50 neonates and found 71 of 125 feeding tubes to be contaminated with significant bacterial growth.[13] Of these neonates studied, if the feeding tube was contaminated, this condition was correlated to feeding intolerance ($P < .05$). Necrotizing enterocolitis developed in 7 neonates with $>10^5$ colony-forming units (CFU)/mL growth in their feeding tube. While this is an older study, it exemplifies why these ports will need to be cleaned by nursing staff or families at home on a routine basis to remove residue.

To our knowledge, no studies have been published investigating contamination of the new connector as of this writing date. There are commercial cleaning devices on the market, and we suggest using either a commercial brush or toothbrush and water daily and as needed. Purified water or saline would need to be used in a clinical setting.[14]

Special Considerations for Patients and Caregivers at Home

Blenderized Formulas

Blenderized formulas have become more popular in recent years for many reasons. These reasons include lack of reimbursement, need to treat enteral feeding intolerance, desire to consume the same nutrition as the rest of the family, and concern about ingredients in commercial formulas. While this started as a patient-driven effort, it has gained acceptance by clinicians as reports of success, both anecdotal and evidence based, appear in the literature.[15–17] While many recipes developed by dietitians tend to be similar in composition, variability is tailored to specific patient needs. With that variability comes differences in viscosity. Most blenderized diets are administered as a bolus using a syringe as a funnel for ease of administration. With the new ENFit system, patients anticipate problems with blenderized formula administration. One study did look at this issue and used a commercially available blenderized diet product. There was no difference using a wider tip syringe vs the ENFit syringe for blenderized diet administration.[18] Another study by Mundi et al[19] observed a need for increased force with the ENFit connector to administer blenderized formulas compared with traditional connectors, but this study was conducted with device prototypes and not with FDA-approved products. Currently, the FDA and other independent laboratories are conducting flow and pressure studies with a variety of tubes and a variety of formulas, including blenderized diets.

Many patients in the home, particularly children, receive a home-prepared blenderized diet, which tends to be thicker than commercial products. While it remains to be seen if ENFit syringes do result in longer administration times for blenderized diets, one potential solution is to give additionally prescribed water in the feeding. Many patients require additional free water above what is provided in the daily homemade formula volume. This, of course, needs to be based on patients' fluid tolerance and calculated as part of the EN prescription.

Outpatient Medication Administration Issues

Patients of any age who have a long-term enteral access device typically require liquid medication administration through their

feeding tube. The ENFit syringe system allows for safe withdrawal from a medication bottle and safe connection to the enteral access device. While the latter connections of the ENFit syringe to the ENFit feeding system ensure patient safety, there are still concerns about medication withdrawal from a liquid medication container. Caregivers may need to use a medication straw (see Supplementary Material, Procedure 2 available online at http://ncp.sagepub.com/supplemental) that is placed within a dome covering the bottle opening, or they may need to attach the syringe to a bottle cap adapter that has an ENFit-compatible top. Two issues need to be ensured in the process of medication withdrawal: prevention of medication wastage from retained medication in or outside of the straw and spillage or leakage of medication from around the bottle cap adapter. Medications will also need to continue to be dispensed with childproof caps.

Both home care enteral supply companies and outpatient retail pharmacies need to be prepared to dispense supplies that will allow for safe medication preparation and administration, including syringes, bottle cap adapters, straws, or both. Commercial pharmacies are going to need to have ready access to ENFit-compatible supplies as many of these pharmacies dispense medications for patients with long-term enteral access devices. Enteral product suppliers such as durable medical equipment companies will need to send ENFit syringes and medication bottle adapters to patients as well. A step-by-step procedure for medication delivery for patients in the home setting can be found in the Supplementary Material (Procedure 2).

Patient and Family Education

Education of patients and caregivers is a duty all disciplines who work with enterally fed patients need to embrace. Long-term enteral access devices will not all change over at the same time, nor will syringes and medication bottles. A proactive plan to educate patients and caregivers on what to expect and how to safely administer feedings and medications is essential. In addition, home health agencies and referring facilities such as physician offices, urgent care centers, and specialty centers need to be prepared for this change if they replace feeding tubes or administer medications. This is a major practice transition that will affect all sectors of the healthcare system. Those in hospitals with expertise in enteral nutrition support can use GEDSA and the American Society for Parenteral and Enteral Nutrition (ASPEN)–approved education materials to provide to patients. The use of an illustrative poster and videos can allow those who are not proficient in the English language to understand how to use the ENFit system properly.

Summary

New enteral connectors are now in the marketplace for the purpose of improving patient safety. Becoming aware of the benefits and challenges of the new system is crucial during this transition period. Communication between device manufacturers, suppliers, clinicians, and patients is critical to the full implementation of this safety feature.

Supplementary Material

Procedures 1 and 2 are available online at http://ncp.sagepub.com/supplemental.

Statement of Authorship

P. Guenter and B. Lyman have equally contributed to and drafted the manuscript, critically revised the manuscript, agree to be fully accountable for ensuring the integrity and accuracy of the work, and read and approved the final manuscript.

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