Being Prepared and Adopting New Enteral Connectors: 

Interview with Peggi Guenter, PhD, RN, FAAN
Senior Director for Clinical Practice, Quality, and Advocacy of the American Society for Parenteral and Enteral Nutrition

Why do enteral nutrition (EN) connectors need to change?

To reduce the frequency of medical tubing misconnections. An international group of clinicians, manufacturers and regulators, such as the FDA, is collaborating with the International Organization of Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop ISO 80369 standards. Unique international standard designs will promote better patient safety and help ensure that connectors for unrelated delivery systems are incompatible. The program that is helping introduce the new standards is called the Stay Connected initiative for using safer connectors. Much of the information in this article came from the extensive FAQ documents on that site.

The purpose of the new enteral connector is to help reduce the risk of enteral tube feeding misconnections and improve patient safety. Since 1973 there have been multiple patient deaths and near fatal events because tube feeding or oral/enteral medications were delivered into an IV or other non-entaler connection. Despite education, sentinel event alerts, and warnings from safety and regulatory agencies, these misconnections continue to happen because the system allows it. The new enteral connector standard, called ENFit, will be found on all enteral devices including feeding tubes, administration sets, and medication, flush, and bolus feed syringes.

When will this happen?

In the US, the new ENFit connector is already on administration sets or bags and can be found in home care, hospital and long-term care settings. These sets came onto the market in late spring of 2015 and require a transition adapter to connect them to current feeding tubes. In the US in the first half of 2016, enteral syringes and new feeding tubes with the ENFit connector will begin entering the market. Due to California law, this mandatory transition needs to happen in the by July of 2016. Once that transition is fully made, the transition adapter will no longer be needed except for connection in patients with long-term feeding tubes.

What about patients who have current feeding tubes in place, how will they receive their tube feeding formula?

Patients, particularly those with long-term feeding tubes will not need to immediately have another tube placed but when they are normally ready for a tube change, they will receive one with an EN-
Enteral Connectors: Long Term Care and Home Care

Kristy Klug, RD, LDN

Tubing is used in the healthcare setting to connect patients to medical devices for the provision of liquids and gases. Tubing misconnections can occur when tubing from one medical device is inadvertently connected to a functionally dissimilar tube of a patient, allowing for medical liquids or gases to be delivered into parts of the body for which they were not intended. For example, tubing from an enteral feeding accidentally connected to an intravascular (IV) port, allowing enteral nutrition to be administered into the patient’s bloodstream. The results of these misconnections can be devastating, often leading to severe patient harm including permanent injury or death.1 Industry changes are occurring across the healthcare continuum to create safer connections for all patients. In this article, we will discuss the introduction of the new ENFit enteral connectors in the long term care and home care settings.

Though many factors can contribute to tubing misconnections, the universal design of luer connectors allows for functional connection between unrelated delivery systems such as IV, enteral, respiratory, epidural, intrathecal, and other tubing systems that are not intended to connect.2 Making tubing connections is a routine task in healthcare, and it is not uncommon for a typical patient to be connected to multiple different delivery systems at once for the administration of nutrition, hydration, medication, oxygen, and other therapies. The compatible luer design among these various patient delivery systems makes the risk for misconnections high, with each event carrying the potential for a fatal outcome.

Other human and design factors can facilitate tubing misconnections such as poor lighting, unintended use of tubing and adapters, similar appearance of IV and enteral solutions, close proximity of multiple lines, and stress, fatigue or time pressure of the practitioner.1 Though misconnections result from performance errors, the literature strongly supports that these errors occur without the conscious awareness or control of the practitioner.1 At the time the misconnection occurs, the practitioner is unable to identify that she has made an error, but is fully knowledgeable of the danger posed by connecting wrong routes. In home care, patients rely on family members and caregivers, often without medical backgrounds, to be trained on medical devices such as ventilators, suction machines, enteral feeding pumps or IV pumps. It only takes one incident, one mistake, one time among the multiple connections that are made every single day on any given patient. Thus we find compelling suggestions in the literature that recommend efforts be focused on redesigning systems to make a connection physically impossible when attempting to connect to the wrong route.1

“A 24-year-old woman was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready-to-hand enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, which the woman had received on previous admissions, pulled regular intravenous tubing from the floor stock, spiked the bag, and started the infusion of tube feeding through the patient’s peripherally inserted central catheter line. The fetus died – and then the mother, after several hours of excruciating pain.”1

As you might suspect with any voluntary adverse event reporting system, it is believed that the reports of enteral misconnections found in literature fall far short of the number of actual cases.1 One of the first published cases dates back to 1972 and involved an accidental intravenous administration of breast milk.1,2 In a review of the United States Pharmacopeia (USP) Medication Errors Reporting (MER) Program between January 2000 through December 2006, 24 incidents were revealed involving formula, medications or fluids intended for the enteral route but administered via the wrong route.1 Of those 24 case reports, 16 involved IV administration of enteral medication with 25% resulting in a sentinel (life-threatening or fatal) event.1 Many of the cases reported the use of an IV syringe to dispense, prepare, or administer the medication, and subsequently the syringe was accidentally attached to the patient’s IV line.1 In a literature review of case reports published between 1972 and 2010 involving misconnections of formula intended for the enteral route but administered intravenously, reviewers identified 32 reports that document a total of 116 cases with 21 resulting in patient death.2 Of the 32 reports, the top threat identified was compatible (luer) tubing connectors, and the top recommendation was to redesign connectors to prevent misconnection and eliminate cross-system compatible connectors.2 As early as 1979, the healthcare industry has recognized the need for enteral feeding connectors that are incompatible with intravascular access, yet despite warnings since 1986 from expert organizations and regulatory agencies, the number of misconnections continue to grow.1

“In all of these stories there are two sets of victims, the patient and family,
as well as the clinician. Clinicians never mean to make these mistakes, but they do – because they can.” –Peggi Guenter, PhD, RN

In April 2006, the Joint Commission released a sentinel event alert in response to a number of tubing misconceptions that centered around the theme, “if it can happen, it will happen.” The alert urges product manufacturers to develop connectors that have “designed incompatibility” features which would use forcing functions to physically prevent dangerous misconceptions from occurring. Over the past several years, representatives from regulatory agencies such as the FDA and Joint Commission, private and public organizations including United States Pharmacopeia (USP), Institution for Safe Medication Practices (ISMP), ECRI Institute, American Society for Parenteral and Enteral Nutrition (ASPEN), as well as healthcare professionals and industry manufacturers have come together in a partnership to set standards for the redesign of enteral connectors with one common goal: improving patient safety. These standards defined by the International Organization of Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) and recognized by the FDA require that small-bore connectors for liquids and gases in healthcare applications not be compatible with others in the series, are rigid or semi-rigid, pass a miss-connection test, and are not compatible with luer or needleless connector ports (ISO-80369-3). Of note, color specifications are not included in the design change, thus nurses or other clinicians will not be able to assume, for example, that all purple connectors are enteral. Enteral connectors are the first to transition to a safer connector design in a series of small-bore connectors that also includes neuraxial applications, medical gases and respiratory devices, limb cuff inflation devices and intravascular access for which the existing luer connector will be maintained.

Transition Timeline
The new ENFit enteral connectors will impact the entire feeding system and will be introduced in a three-step approach to ease the transition. The transition will begin with temporary transition connectors on the ends of administra-
not be compatible with the new ENFit connector system. If you are at a facility where your pharmacy prepares and pre-fills certain medications before delivering to the patient, the ordered medication will need to specify the type of syringe and route of administration so the pharmacy knows what type of syringe to use. This concept may require additional education for prescribers who are not accustomed to ordering medications in this way. You may also need to work with your healthcare technology group to update electronic medical record (EMR) order sets to accommodate these changes.

**Inventory Management**

Identifying the type of syringes needed for your patient population will drive inventory levels and assist purchasing departments in reducing the inventory of current connectors as the demand for ENFit connectors grows. Materials management staff in long-term care facilities will need to understand the transition timeline and plan for additional storage space in the central supply, nursing units, and on the floor. Maintaining adequate inventory of both the current connector system and the new ENFit connector system without excess supply, returns or waste will require a comprehensive analysis of supplies currently in use along with careful planning and ongoing communication throughout the entire organization.

**Home Care Considerations**

Estimates suggest that more than 344,000 individuals of all ages in the US receive enteral nutrition in the home setting. Clinicians practicing in home health may encounter other concerns unique to the home setting in addition to the items that have already been addressed. Many home enteral nutrition (HEN) patients have been tube feeding for years, and as with any change, the redesign of supplies they are familiar with may seem alarming or even daunting. Providing education on both the safety implications of the connector changes as well as the new design itself will help patients become familiar with the impending changes and allows them adequate time to understand how this industry conversion will affect their unique situation.

Many patients receive medications through their feeding tube multiple times throughout the day—a known risk for tube clogging even with the current connector system.

Some HEN patients administer home-prepared blenderized feedings through their feeding tube as their primary source of nutrition. Concerns have been raised on how the new ENFit design might affect the flow rate of these viscous substances, noting the 2.9 mm opening on the ENFit connector is smaller than the 4.3 mm tapered diameter of a catheter tip syringe. A testing protocol was designed to gather data specific to these concerns, and the findings were released in a newsletter publication from the Oley Foundation. The purpose of the experiment was to determine the flow rate of blended diet formulas through a number of available feeding tubes with the current connector system as compared to the new ENFit connector system. The experiment measured the viscosity of various substances meant to replicate blended formulas used in practice, and performed gravity flow and pressure testing to determine the difference in flow rates or pressure required to administer formulas through a 60 ml syringe. The results suggest that there is no significant difference in the amount of pressure needed to push through the ENFit connector compared to the catheter tip syringe, and overall the flow and pressure requirements are essentially the same. The lack of available tubes with the ENFit connector presents a limitation to this study design in that all tubes that were used in experiments were tubes with the current female connector system. Product manufacturers should perform testing on their own line of enteral devices and make samples available to the healthcare industry to allow for evaluation by frontline nurses and clinicians.

Many patients receive medications through their feeding tube multiple times throughout the day—a known risk for tube clogging even with the current connector system. As with blenderized diets, the new connector system is expected to yield comparable results to the current connector system. There are several published guidelines on techniques recommended to reduce the risk of tube clogging when administering medications, which can be extrapolated to the use with ENFit connectors. Practice recommendations from ASPEN suggest administering properly diluted medications separately with a water flush given before, between and after medication administration. However, commonly we see patients as well as clinicians mixing multiple medications together to give at once through the feeding tube without flushing with water before or between subsequent medications which can increase the risk for tube clogging, regardless of the connector system in use.

Some patients currently utilizing feeding sets with the new transition adapter have reported issues with connectors leaking or cracking. The connector design is subjected to testing for stress cracking and leak prevention as well as resistance to separation from unscrewing. Although manufacturers confirm that their products meet the new ISO standard requirements, as with any product, the potential for malfunction still exists. To help prevent these issues from occurring, several recommendations may be followed. To eliminate the risk of cracking due to overtightening, only hand-tighten the transition connector to the ENFit connector and do not use a “tool” such as a hemostat to tighten the connection. A small gap should remain between the base of the transition adapter and the ENFit connector. To prevent leaking, when inserting the transition adapter into the feeding port, use a clockwise twisting motion. Twist-
ing counter clockwise could unscrew the transition adapter from the ENFit connector, breaking the seal between each piece and allowing leakage to occur. While every effort is being made to ensure these issues are being addressed, manufacturers are urging users who experience malfunctions to contact them directly and make a formal report so the proper evaluation of their product can take place.

Pediatric patients requiring home enteral nutrition (HEN) have certain supplies that differ from the adult population. Popular among them are the low profile gastrostomy tube devices. These tubes will not be changing the connection at the point the extension set inserts into the skin-level device, nor will the balloon port on these devices change. However, the proximal end of the extension set that connects to administration sets and syringes will be changed to the new ENFit male connector. An added benefit of the new ENFit connection system is the manner in which the connectors twist and lock together, making it less likely that a feeding becomes disconnected, for example, in the middle of the night and ends up “feeding the bed” instead of the patient.

Conclusion

The redesign of enteral connectors aims to elevate the standards of patient safety by preventing tragic outcomes resulting from tubing misconnection errors. The new ENFit design uses engineering controls with specific requirements that create incompatibility between functionally dissimilar tubes, making it physically impossible for a user to make a potentially lethal misconnection.

ENFit connectors will be introduced in a phased approach to ease the transition from the current connector system. This global initiative will affect multiple levels of throughout organizations, and generating awareness to all staff is necessary to ensure a smooth conversion. Providers should begin evaluating and planning now for the coming changes, and develop processes and procedures that incorporate the new ENFit connectors into practice. Safety measures should be taken to mitigate the risk for tubing misconnections throughout the transition phase until the conversion to the new design is completed.

During the development of new connector standards, current practice was considered to avoid unintended consequences or disruption of therapy. No clinically significant differences were found when comparing flow rates for differing viscosities of formula, including a blenderized diet prototype, using the current connector system and the new ENFit connector system.

Overall, the number of critical and potentially fatal events may be abolished with the collaborative efforts of regulatory agencies, professional organizations, device manufacturers, and clinicians throughout the healthcare industry by adopting the new ENFit connector standards for the enteral delivery of medications, hydration and enteral formulas.

Stay Connected

The Global Enteral Device Supplies Association (GEDSA) is a group composed of leading manufacturers and distributors of enteral feeding products that was formed to help introduce and encourage adoption of international standards in medical device tubing connectors within the healthcare industry. Through their “Stay Connected” initiative, GEDSA hopes to enhance patient safety by raising awareness and facilitating the transition to safer medical connectors. For more information, transition checklists and additional resources, visit www.StayConnected.org.

References


Kristy Klug, RD, LDN is the Clinical Manager at the Carolinas HealthCare System and is responsible for the education and supervision of the delivery of enteral nutrition in homecare. Speaking at several medical conferences, Ms. Klug has recently presented at a regional ASPEN conference on the topic; New Enteral Connectors, Improving Safety. Ms. Klug has received several awards for her educational clinical work.
Fit connector. In the meantime, they will need to use the transition set to deliver their feedings from the new administration set into the current feeding tubes. The new administration sets have the ENFit female connector instead of the stepped or Christmas tree connector.

The transition connector is fitted with both the new ENFit and stepped Christmas tree design to allow a connection of the new ENFit administration sets with current feeding tube system ports. There have been some problems that some clinicians and home health care users are experiencing, specifically, the over- or under-tightening of the white transition connector onto the mating ENFit female connector on feeding admin sets resulting in leaks and having to replace some enteral components. You need to contact your manufacturer directly but some recommendations to overcome these problems include the following steps:

- Clean and thoroughly dry the feeding tube port and connector on the pump set prior to use.
- For low profile extension tubing, wash and rinse thoroughly in-between use.
- Using warm soapy water helps to eliminate formula residue and rinse thoroughly.
- Always follow the manufacturer’s directions for use and instructions provided by your healthcare provider.
- Push and twist the white transitional connector into the feeding tube port. Always twist clockwise.
- Be careful not to overtighten.

What about patients who have drainage tubes and need enteral nutrition?

Patients who have a gastric-jejunal feeding tube often use the gastric port for drainage or venting of the stomach. They often use a drainage bag that may not have the ENFit connector. If the drainage or gastric port of the feeding tube has an ENFit connector, an adapter type device may be required to hook that ENFit connector to a drainage bag or venting bag. Some of the drainage ports may be ENFit and some may not. Also some of the venting bags may also be ENFit compatible. Consult the manufacturers to see how your specific line of tubes and bags will be designed.

Will gastrostomy tube (G-tube) skin-level devices be changed in any way? If so, how?

Not the devices themselves. Connectors on skin-level feeding devices are out of scope of the new ISO 80369-3 design standards, so those specific device connectors will not change. At the point that extension sets attach to these devices the connection will likely remain the same since those connection points are not affected by the standard. However, the other end of the extension set (often called the proximal end) that connects to administration sets and syringes will have the new ENFit male connector.

Will using a transition connector on a bolus extension set make the hole in the bolus extension–syringe connection smaller?

Yes, the hole will likely be smaller than that of the current catheter-tip syringes, however it won’t be smaller than the end of the extension set that connects to a low-profile device. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration.

What will happen to Salem sump feeding applications since they are not going to undergo any of the new standard changes (Salem sump tubes which are large bore tubes are exempt). Have any provisions been made for these tubes such as special adapters?

Salem sump tubes are out of scope of the small bore connector standard as they are not indicated as feeding tubes but are drainage tubes. On occasion, a patient is fed through a salem sump to try to see if that patient will tolerate enteral nutrition. If they cannot, one can put the tube back to suction or drainage. If they can tolerate tube feedings for a day or two, the tube can then be changed to a nasonenteric feeding tube. In the meantime if the feeding administration set is ENFit, it will not fit on the end of the Salem sump. For this, an adapter has been developed to allow the Salem sump to be ENFit compatible and the enteral nutrition trial can be done.

Medication Delivery Issues

Will medication delivery through feeding tubes be different?

Medication delivery will be altered in that a different type of enteral medication port will be necessary. No longer will luer syringes or catheter tip syringes fit into an ENFit medication port. So prescribing, preparation, and administration of enteral medications will require specific protocols and lines of communication will need to be enhanced. No longer should the prescriber simply write for an enteral medication to be delivered “po” as the right type of syringe will need to be employed.

Another issue with medication delivery is the issue of low dose accuracy. Because the ENFit connector has a reversed orientation, that is, the syringe tip is female and not male, there is a larger amount of dead space in the syringe tip. That can lead to medication inaccuracy depending on whether it is filled from a cup or from a filling device. Currently, industry is working on some innovative syringe designs to try to overcome this overdosing or underdosing concerns in small volume medication delivery. Stay tuned to StayConnected.org website for latest on those low dose medication syringes.

Since most clinicians use different methods/devices to crush drugs, there is a question about un-uniform drug consistencies that may result in more frequent feeding tube clogs. That is currently an issue if large drug chunks have not been sufficiently crushed. This requires nursing and pharmacy personnel to discuss proper medication crushing and delivery processes so that medications are properly administered and do not clog feeding tubes.

Nursing Procedures

Does this change require any other nursing procedures?

Enteral nutrition delivery and use of a feeding tube require many nursing procedures which include:

- Verification of tube position
- Checking gastric residuals
- Flushing tube
• Administering feeding formula or human breast milk
• Administering medications
• Venting or draining the tube as needed

As we discussed above, administration of medications may need some alteration in nursing procedures. Other procedures such as verification of tube position, checking residuals, flushing the tube and administering the formulas will require use of the new administration sets, syringes and feeding tubes. The venting and draining of the tube may require an adaptor of some kind but the procedure should remain the same. A new procedure which may need to be built into care protocols include cleaning the external end of the feeding tube because of the male end and the threads inside that end. Suggested cleaning includes daily rinsing of the tube with water or saline and use of a soft brush to remove any formula or medication debris. Some companies are developing a cleaning device or modifying their tube to for less build up around the end. Look for innovation in this area. Overall the nursing procedure workflow may be different during transition period than it will be when change is completed.

Will there be a standard color for the new ENFit connector?

Color coding is not included in the 80369-3 standards. The standards will only address the new ENFit connector’s shape and size. These newly developed engineering controls (forcing functions) make it highly unlikely to bring two unintended connectors together, a development that seems more secure as opposed to relying on memorization of a specific color scheme. While you might see color used for enteral connectors, it is not a requirement.

Will thicker formulas and blenderized foods pass through the new ENFit connector?

The ISO 80369-3 enteral feeding design standards were developed with current practice in mind and specific requirements to avoid any disruption of therapy. The bore size (or hole) in the ENFit connector was designed to be consistent with the current connector (commonly called “Christmas tree” or “stepped adapter”). Therefore, feeding through devices with the ENFit connector is intended to be consistent with current practice. The enteral-specific syringes with the new ENFit connector will likely have a smaller hole than the catheter-tip syringe. However the hole will not likely be smaller than the patient access end of the (bolus) extension set opening on most low-profile devices. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration. For other devices, the industry is currently evaluating the impact of a smaller size of the hole. For more information, contact the manufacturer of the enteral device directly.

Dr. Peggi Guenter is the Director for Clinical Practice, Advocacy, and Research Affairs for the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Dr. Guenter is a Certified Nutrition Support Nurse and spent over 20 years in clinical practice caring for patients receiving enteral and parenteral nutrition. She has authored over 90 research papers, clinical articles, chapters, standards, guidelines, and books on the topic of nutrition support. She currently is serving on the Association for Advancement in Medical Instrumentation (AAMI) International working group on enteral connector redesign.

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Saxe Healthcare Communications
P.O. Box 1282, Burlington, VT 05402
info@saxecommunications.com
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Learning Objectives
After completing this activity, the learner will be able to:
1. Describe safety features of the new enteral connectors throughout the EN delivery system
2. Identify key components necessary for the transition to the new enteral connectors.
3. Identify practice considerations of the new ENFit design in the long term care and home care settings.

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Content Experts: Peggi Guenter, PhD, RN, FAAN and Kristy Klug, RD, LDN disclosed no conflicts of interest
1. Question: An enteral misconnection is defined as:
   A. Infusing enteral formula into an IV or dialysis catheter
   B. Infusing the wrong enteral formula
   C. Infusing IV solution into the wrong IV port
   D. Infusing gastric medication into the jejunum

2. The purpose of developing a new enteral connector is:
   A. To bring more feeding tubes into the market
   B. To confuse nurses and patients
   C. To improve safety and prevent misconnections
   D. To have enteral connectors better mate with IVs

3. New feeding tubes and syringes will come into the market:
   A. January-March 2015
   B. April-June 2015
   C. October-December 2015
   D. January-March 2016

4. Which type of syringe should be used for enteral medications once the transition to ENFit is made?
   A. Oral syringe
   B. Catheter syringe
   C. Luer IV syringe
   D. ENFit enteral syringe

5. Who in your hospital needs to know about these connector changes?
   A. Pharmacists
   B. Supply chain personnel
   C. Safety officers
   D. All of the above

6. Tubing connections in the healthcare setting:
   A. Are used for the provision of nutrition, hydration, medication, oxygen, and other therapies
   B. Have a universal luer connector among unrelated delivery systems
   C. Can be fatal if a misconnection occurs
   D. All of the above

7. Enteral misconnections are most commonly attributed to which of the following?
   A. The use of RTH enteral bags with IV tubing
   B. Similar appearance of enteral and IV solutions
   C. Universal design of connectors that allows for functional connection between unrelated delivery systems
   D. Inadequate lighting

8. New enteral connectors have which of the following features?
   A. Designed incompatibility with other delivery systems
   B. Specified color
   C. Rigid or semi-rigid
   D. A and C

9. Which syringes will be compatible with the ENFit connector system?
   A. Catheter tip syringes
   B. Luer slip tip syringes
   C. Oral syringes
   D. None of the above

10. Name one way to prevent leaking with the transition adapter.
    A. Use a tool such as hemostats or pliers to tighten the connection
    B. Use a clockwise twisting motion when inserting the transition adapter into the feeding port
    C. Ensure no gap present between the base of the transition adapter and the ENFit connector
    D. All of the above

Participant’s Evaluation

What is the highest degree you have earned (circle one)?
1. Diploma
2. Associate
3. Bachelor’s
4. Master’s
5. Doctorate

Indicate to what degree you met the objectives for this program: Using 1 = strongly disagree to 6 = strongly agree rating scale. Please circle the number that best reflects the extent of your agreement to each statement.

1. Describe safety features of the new enteral connectors throughout the EN delivery system
   Strongly Disagree  Strongly Agree
   1  2  3  4  5  6

2. Identify key components necessary for the transition to the new enteral connectors.
   1  2  3  4  5  6

3. Identify practice considerations of the new ENFit design in the long term care and home care settings.
   1  2  3  4  5  6

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