Safer Enteral Nutrition Syringes

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Ms. Lyman discloses that more than three years ago, she participated in a GEDSA-funded research project, and she serves as co-chair of the GEDSA Clinical Adivosry Board.

Hundreds of thousands of patients receive enteral nutrition (EN) or tube feeding each year in U.S. hospitals, and many more in long-term care and home settings.[1] In addition, these patients receive medications and or supplemental fluids, most often through that feeding tube, using syringes to deliver the medication or fluids. With each of those many medications, usually administered several times a day, a syringe is used and an enteral connection is made between the syringe and the enteral access device. With each connection is the potential for a misconnection or wrong route error.

An enteral misconnection is defined as an inadvertent connection between an enteral feeding system and a non-enteral system such as an intravenous (IV) line, peritoneal dialysis catheter, tracheostomy tube cuff, or medical gas tubing.[2] More than 116 instances of enteral misconnections were reported in a large review, spanning 1972–2010.[3] The severity of this type of error was high and resulted in death in 18% of the patients due to ensuing embolus or sepsis.[3] While this review reports many misconnections, like many other adverse events, enteral misconnections may be greatly underreported.

In a report that included 24 cases of enteral misconnection errors, these events were classified by type. The report found 33% of the errors were sentinel events, which result in permanent injury, a life-threatening situation, and/or death.[2] These misconnections were related to use of IV syringe pumps for EN, preparing enteral medications using IV syringes, and administering ready-to-hang enteral formula with IV tubing.[2] In this report, 13 cases were enteral medications administered intravenously using an IV syringe. This resulted in a 23% rate of life-threatening or fatal outcomes.[2]

In 2013, another report cited 20 cases of inadvertent IV administration of oral medications between 2004 and 2012. In this paper from the Patient Safety Authority (PSA), all the events reached the patient and 20% (n=4) resulted in patient harm, including one death. In many of these cases, oral drugs were administered using an IV syringe.[4]

In a data set provided to these authors by Dr. Mike Cohen of the Institute for Safe Medication Practices (ISMP), as reported to the Medication Errors Reporting Program (MERP), 8 incidents were noted between 2000 and 2019. In each of these cases, medication or fluid not intended for IV administration was given intravenously. Since 2012, after all the above reports, an additional 3 incidents occurred with this same scenario, where the nurse administered a non-IV medication using a parenteral syringe, with one of the three patients expiring.

Adding a patient-level perspective to these sentinel events greatly reinforces the need for change. Here is one such unfortunate event:

A 24-year-old woman was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready-to-hang 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 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.[2]

While this incident did not involve a syringe, it involved enteral connectors of which have been changed to a safer design.

Enteral delivery systems include the feeding tube or access device, an administration set or bag, a feeding pump, and/or an enteral syringe. This system can have many connections, again, each with a chance of a misconnection. In response to reported misconnections, the International Organization for Standardization (ISO) created and published the ISO 80369 standard for small-bore connectors in 2010.[5] The first clinical platform of this new connector standard was ISO 80369-3 for enteral feeding.[6,7] The first connectors on the U.S. market were launched on enteral administration sets in 2014. As seen in the drawing in **Figure 1**, the ENFit connector is no longer a tapered end but requires a twisting motion to connect the two ends, with the feeding tube end being the male end and the delivery set or syringe being the female end. This is called "design incompatibility," because these connectors do not work with any non-enteral medical devices.

New ISO 80369-3 compliant connector (known as ENFit) enteral syringes with volumes ranging from 1 mL to 100 mL are now available to "force function"—meaning the clinician can only deliver the medication via another ENFit-compatible connection, such as a feeding tube, and not an IV catheter. A concern early on with the new ENFit syringe was dosing accuracy of small-volume medications due to the reverse orientation of the entire enteral system,

Figure 1. ENFit® Connector

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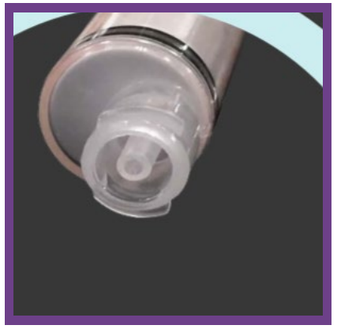
Figure 2. ENFit® Low Dose Tip Syringe



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> **Since the transition to these connectors, there have been zero wrong route medication errors associated with these connectors in the United Kingdom.**

as the dead space volume was deemed to be significant. To mitigate this problem, a low dose tip (LDT) syringe was developed and tested and has been shown to be accurate.[8] As seen in **Figure 2**, there is an internal stem in the LDT syringe to mitigate the dead space concern.

While most of the United Kingdom and Europe has already transitioned to ENFit, progress is slow in North America. Since the transition to these connectors, there have been zero wrong route medication errors associated with these connectors in the U.K., indicating this is a successful patient safety initiative.[9] Overall, this transition involves changing approximately 200 products and requires education of staff and patients, making it a mega change in practice for most institutions. However, the Global Enteral Device Supplier Association (GEDSA) has many resources on their website (www.stayconnected.org) to assist with the planning and implementation of the transition. In addition, GEDSA has a multidisciplinary Clinical Advisory Board of clinicians who have successfully transitioned to ENFit connectors and serve as resources for institutions seeking assistance.

There are several reasons why this transition may be slower in the United States as compared to the global market. These include, first, that the conversion is not mandatory as regulated by the U.S. Food and Drug Administration (FDA), The Joint Commission, and any payers. Second, the United States has a decentralized healthcare system that does not lend itself to concerted action across the country. Third, healthcare systems have had competing priorities over the past few years, such as implementing electronic health records systems and now the COVID-19 pandemic, which has paused conversion efforts to focus on the priority of the virus; hospitals are reporting that the transition was not a priority and, in addition, manufacturers' representatives cannot get into the hospitals to help with the conversions. Finally, some facilities remain unconvinced of the need for conversion or its benefits.

In order to stop ongoing misconnections with medication delivery, it is imperative that the proper syringes are available and used for all medication preparation and administration, particularly enteral medications. This is especially important during this transition period in the United States, where ENFit enteral syringes are slowly replacing legacy syringes for enteral use in hospitals. Suggested practices to prevent this ongoing risk of wrong route error include the following steps:

1. Be sure providers order medications with specific route noted (via nasogastric tube versus oral)

2. Communicate specific medication route with pharmacy in as many ways as possible

3. Have pharmacy prepare medications and deliver to patient care area in enteral syringes

4. Have enteral syringes of all needed sizes available at the nurses' medication preparation areas

5. Prepare an injectable medication to be administered enterally with an ENFit blunt tip needle and ENFit syringe.

6. Send a zip-close bag of ENFit supplies home with patients to allow them to give medications at home. (Some institutions send home adapters to allow for legacy syringes to be used with ENFit feeding tubes, but workarounds should be time-limited)

7. Avoid workarounds like adapters that allow ENFit syringes to become legacy or vice versa.

8. Amend durable medical equipment orders to include ENFit syringes so these companies can provide ongoing supplies to patients.

9. Educate families and staff about this change prior to, during, and after the transition, with opportunities for hands-on practice with the new supplies.

10. Encourage retail pharmacies to stock enteral syringes for over-the-counter purchase by home EN families. (These syringes are now available on Amazon and other internet sources.)

11. Prepare medications using the steps outlined in the medication delivery infographs for inpatient and home settings.[10,11]

Use of appropriate enteral syringes can prevent misconnections such as those incidents illustrated in the case reports outlined in this paper. This important global patient safety initiative to prevent enteral misconnections is just the first of many connector changes to come, with neuraxial connectors changing next. The lessons learned from this first transition experience will be a template for how the next connector transitions can be implemented. Patient safety builds one step at a time, but the momentum depends on the work of individual institutions and clinicians dedicated to making the healthcare system a safer environment.

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