

# Misconnections and the Emergence of **Enteral Nutrition Connectors** for Patient Safety

By Peggi Guenter, PhD, RN, FAAN, FASPEN and Mike Cusack

**M**any home infusion providers include enteral nutrition in their portfolio of services. The need to provide safe care technology at home is even more important perhaps than in hospitals because most often patients and/or caregivers, rather than trained professionals, are delivering therapy. Given that circumstance, transitioning to safe enteral connectors is best practice and the time to convert to safer products for home enteral nutrition is now.

## SPARKING ACTION

The effort to develop an international standard for health care tubing connectors has its roots in a 2007 report from the World Health Organization (WHO) which listed a set of 9 “patient safety solutions” that could help reduce the number of injurious health care-related incidents.<sup>1</sup> That list prominently referenced catheter and tubing misconnections as one of the key issues requiring a resolution. Although the issue was known to caregivers and equipment makers, it was the WHO’s report among others (U.S. Food and Drug Administration and Institute for Safe Medication Practices for example) that sparked action in a coordinated way.<sup>2-5</sup>

## UNDERSTANDING MISCONNECTIONS

A tubing misconnection occurs when a fluid or medication is accidentally delivered into the wrong vessel, such as veins, organs, or other destinations. The ramifications are serious, ranging from discomfort to infections and even death. These unfortunate situations are possible as long as the connectors that are used for a variety of incompatible therapies can more or less

physically connect with each other.<sup>6</sup> Reported examples of tubing misconnections include:<sup>7</sup>

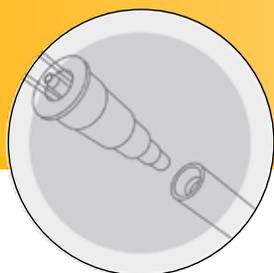
- IV tubing misconnected to a nasal cannula used to deliver oxygen; the patient survived after being treated for congestive heart failure
- Epidural infusion set connected to a peripheral IV, delivering epidural medication to bloodstream, resulting in patient death
- Feeding tube connected to an in-line ventilator suction catheter, delivering feeding contents into the patient’s lungs, resulting in patient death
- Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff, delivering air to the bloodstream, resulting in patient death
- Feeding tube coupled with an IV line of a pregnant woman, resulting in enteral nutrition delivered directly into the bloodstream, resulting in patient death (and that of her 35-week-old fetus)

## INCIDENCE AND IMPACT OF ENTERAL MISCONNECTIONS

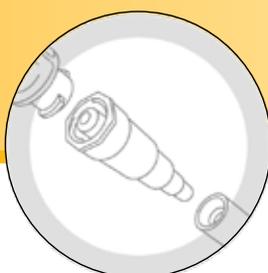
An enteral misconnection is defined as an inadvertent connection between an enteral feeding system and a non-enteral system such as an intravascular line, peritoneal dialysis catheter, tracheostomy tube cuff, or medical gas tubing.<sup>8</sup> While many home patients only have an enteral access device, there is a subset of complex patients at home with multiple therapies that may include intravenous access, tracheostomies, drainage catheters, etc. More than 116 instances of enteral misconnections were reported in a large review, spanning 1972–2010, the most recent data collection effort of its kind.<sup>9</sup> The severity of this type of error was high and resulted in death in 18%

**Tubing misconnections can be deadly. Feeding tubes using enteral nutrition connectors are one component of a system that will help reduce errors.**

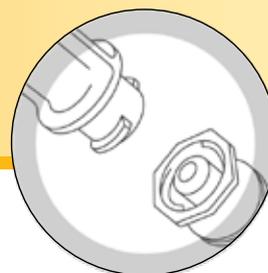
This current feeding tube can potentially be connected to another tube not intended for feeding.



This temporary transition set, with a new female connector, allows the current feeding tube port to fit until the new enteral feeding tubes are available.



The new device, previously a male connector, is now a female connector. The feeding tube port for the administration set will change from female to male.



Source: GEDSA

of the patients due to ensuing embolus or sepsis. Like other voluntary adverse event reporting systems, enteral misconnections may be greatly underreported. Despite a 2006 Joint Commission Sentinel Event Alert, enteral misconnections continue to be reported in the literature.<sup>2,9,10</sup>

Enteral misconnection errors were classified by type in a report which included 24 cases of enteral nutrition (EN) misconnections with 33% leading to sentinel events which are permanent injury, life-threatening situation, and/or death. These misconnections were related to use of IV syringe pumps, use of ready-to-hang formula and IV tubing, enteral medications using IV syringes, and other solutions intended for the enteral route given IV.<sup>8</sup> In 2013, Pennsylvania Patient Safety Authority reported 20 cases of inadvertent IV administration of oral medications between 2004 and 2012. All of the events reached the patient, and 20% (n = 4) resulted in patient harm, including one death. Oral drugs were administered using a parenteral syringe in many of these cases.<sup>11</sup>

**ECONOMIC COST OF COMPLICATIONS**

The economic impact of in-hospital fatalities can be quantified. Costs can be quantified using reported health care costs, and do not include human suffering or lost productivity. The Agency for Healthcare Research and Quality's analysis of 765,651 hospital patient deaths in 2007 found that the average cost of hospital stays in which patients died was \$26,035, which was 2.7 times higher

than those patients who were discharged alive.<sup>12</sup> The total cost of hospital stays for patients who died in the institution in that year was about \$20 billion. These expenses do not include malpractice lawsuits which add another layer of cost to the institution and/or clinicians. When a sentinel event occurs, such as the sepsis that happens when enteral nutrition or medications are administered intravenously, the mean cost per hospital stay is the most expensive diagnosis, more than \$18,000 in 2013. Hospitalizations from sepsis are 70% more expensive than the average hospital stay.<sup>13</sup> An important goal of home care is prevention of hospital readmissions, thus preventing misconnections should be a factor in this goal.

**DEVELOPMENT OF AN ENTERAL CONNECTOR STANDARD**

Armed with the information on safety risks, the International Standards Organization (ISO) 80369 standard for small bore connectors was created and published in 2010.<sup>14</sup> The ISO 80369 series is a family of small-bore connectors created by ISO to maximize patient safety by reducing the risk of medical tubing misconnections. The first clinical implementation was ISO 80369-3 for enteral feeding.<sup>15</sup> The first connectors on the U.S. market were launched on enteral administration sets in 2014.

**THE ENFIT CONVERSION PROCESS**

The primary challenge was to help health care systems and their constituents successfully convert to the ISO 80369-3 standard. Serious

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discussion among health care leaders ultimately led to the formation, in 2013, of the Global Enteral Device Supplier Association (GEDSA). The non-profit trade group included manufacturers, distributors, and suppliers worldwide, with the shared goal of introducing international standards for health care tubing connectors. In order to help caregivers and manufacturers alike, GEDSA resolved to increase the flow of information among its various constituencies and to introduce the new international standards for health care tubing connectors efficiently and rapidly. GEDSA also united behind ENFit, its branded ISO 80369-3 compliant connector, and supported it with extensive engineering and human factors studies.<sup>16</sup>

To make the transition to ENFit connectors, health care clinicians, including physicians, nurses, pharmacists, dietitians, and supply chain specialists are all part of the process. GEDSA developed a series of checklists for all stakeholders, in all settings. GEDSA branded its campaign, *Stay Connected*, an initiative for adopting safer connectors through a three-phase program. Through the Aware, Prepare, and Adopt phases, GEDSA has been promoting a successful transition to safer connectors. The three steps of a successful transition plan are forming a team, building a plan, and executing that plan. The website [www.stayconnected.org](http://www.stayconnected.org), developed by GEDSA, is a resource for organizations preparing to convert to ISO 80369-3 standards. For those facility leaders looking for role models, GEDSA has video case studies of successful transition examples.

Communication, as always, is at the core of a transition. All stakeholders need to be brought in at the ground floor of the process; getting that level of early buy-in is essential. To help drive the process, GEDSA recommends creating a broad multi-disciplinary team. From there, the transition becomes a thorough, detail-management process. The conversion will inevitably touch on more parts of an operation than might be expected. Setting a schedule, and a deadline, can help provide a level of momentum.

### **GEDSA**

Today GEDSA is comprised of over 30 companies around the globe. In addition to its members, GEDSA

has gained support from a number of clinical, research, and accreditation organizations such as Institute for Safe Medication Practices (ISMP), Emergency Care Research Institute (ECRI), The Joint Commission, American Society of Health-System Pharmacists (ASHP), American Society for Parenteral and Enteral Nutrition (ASPEN), and many others.

### **TRANSITION TIPS**

GEDSA has formed an ENFit Clinical Advisory Board (CAB), comprised of expert clinical leaders, including pharmacists, nurses, physicians and more, all of whom have led their facilities through the ENFit conversion. These individuals provide practical tips and lessons learned during their conversions. Their shared knowledge is published in a series of ENFit Transition Tips Sheets, found on [www.stayconnected.org](http://www.stayconnected.org). The CAB suggests home care agencies and home infusion companies start by accessing the tools for organizations and professionals planning to adopt ENFit connectors such as the Transition Checklists. The transition is enhanced when it can be accomplished regionally, that is, local hospitals, home care companies, and long-term care facilities meet and plan a coordinated timeline for conversion.<sup>17</sup> That way, if patients need readmission or emergency department visits, the equipment used at home will match that of the hospital.

### **ENFIT TODAY**

ENFit is approaching 100% in the European Union with the Middle East, Australia, and New Zealand following. Japan is currently in the process of converting and will finish by January 2021, while China and Brazil intend to begin their transitions in 2021. The European Union has been using ENFit connectors for over two years without a single reported adverse event. In North America, the conversion rate is about 30% with many institutions slated to begin conversion in 2020. While transition is crucial for patient safety, it has been somewhat delayed during the COVID-19 pandemic. GEDSA members continue to be supportive and flexible, "Whether your organization has converted, is in the process of converting, or potentially must postpone conversion plans, we are here to support you," they say. Providers planning to convert should contact their specific supplier to determine conversion status, as each manufacturer has a different process for legacy feeding device phase-out and ENFit conversion.

### **ASPEN'S VIEW ON ENFIT**

Since 2006, ASPEN has participated in the development of the ISO standard 80369-3 on safe

enteral connectors. The association has partnered with clinicians, professional and consumer organizations, industry, regulators, and accreditation organizations to push for adoption of safer enteral connectors to prevent adverse events. In its mission for safe and efficacious nutrition care, ASPEN will continue encouraging conversion until all patients have appropriate enteral delivery systems.<sup>18</sup>

## CONCLUSION

Patient safety is the driving reason behind ISO-80369-3 and ENFit. With the advancements in medicine and technology, there is the acknowledgement that health care professionals can do better than in the past—not because they have been wrong or neglectful, but because of the culture of enhanced patient safety. With the conversions to ISO 80369-3, home care clinicians are taking another step forward in delivering safe enteral nutrition.

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