

## **Safe Enteral Connectors: Years of Effort that Support the Need for a U.S. Regulatory Mandate**

The purpose of this document is to strongly encourage a regulatory mandate to ensure a single safer enteral feeding connection system is universally adopted to minimize the risk of tubing misconnections. The process to introduce an International Standard has been the focus of many regulatory, clinical, and subject matter experts over the past ten years. In 2007, the World Health Organization (WHO) launched ‘Nine patient safety solutions’ to help reduce the number of healthcare related adverse incidents, which included avoiding catheter and tubing misconnections as one of the nine<sup>1</sup>. This initiative shed light on the problem and initially set momentum to create a safer connection system. This paper will highlight the efforts that have been made, knowledge gathered and next steps recommended for global adoption of the ISO 80369-3 standard series connector, commonly known as ENFit®. Currently, an extended period of transition has caused supply chain challenges, adoption inconsistencies and patient safety concerns. Mandating the new ISO standard with a clear action plan for the health community will help accelerate action to improve outcomes and quality of life for patients.

### **Background: Small-bore Tubing Misconnections**

When a fluid or medication is accidentally delivered into a vein, organs or other pathways in the human body other than the location for which it was intended, it is called a tubing misconnection. The implications of misconnections can range from discomfort, site infections, neurological complications, and even death. Misconnections are possible as long as the connectors used for enteral, neuraxial, respiratory, and other incompatible therapeutic applications can physically connect to one another. Recent and real examples of tubing misconnections include<sup>2</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

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<sup>1</sup> Hill, C. D. (2010, December 08). WHO launches 'Nine patient safety solutions'. Retrieved from <https://www.who.int/mediacentre/news/releases/2007/pr22/en/>

<sup>2</sup> Center for Devices and Radiological Health. (n.d.). Medical Device Connectors - Examples of Medical Device Misconnections. Retrieved from <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/TubingandLuerMisconnections/ucm313275.htm>

- **Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff**, delivering air to the bloodstream, resulting in patient death
- **Feeding tube was coupled with an IV line of a pregnant woman**, resulting in enteral nutrition delivered directly into the bloodstream; neither the 35-week-old fetus nor the mother survived

Device misconnections are often blamed as human error. Ultimately misconnections occur because tubing device connectors used for multiple therapeutic applications have similarly designed connectors (in many cases Luer slips or Luer locks) and can mechanically fit together. The similar design and widespread use of connectors with similar sizes and compatible fittings is the root cause of a misconnection. Conditions such as multiple connections on one patient, poor lighting, time pressure, fatigue or high stress environments are examples of environmental influences that allow for caregivers to misconnect devices.

Numerous reports of unintentional failures have been published highlighting the implications and examples of misconnections. A 2006 survey of hospitals in the US found that 16 percent of enteral fed patients had experienced a feeding tube mix-up.<sup>3</sup> Further, over an 18 month period in 2005-2006, 33 safety incidents were documented involving oral medication being administered intravenously. In response to the reports, the British National Health Service issued a National Public Safety Alert in early 2007<sup>4</sup>. Additionally, The National Reporting and Learning System in the United Kingdom identified several accounts in relation to tubing misconnections: seven incidents in which epidural medication was delivered intravenously and six cases where intravenous medication was administered via the epidural route<sup>5</sup>.

Many of these misconnections result in medication errors; according to the FDA, each year over 100,000 suspected medication errors are reported to the FDA<sup>6</sup>. Since these reports are not mandated, the actual number of tubing errors is projected to be much higher. In 2010, Simmons *et al* published “Tubing Misconnections: Normalization of Deviance” and cited 116 cases of enteral misconnection in which 21 patients died. Of the 95 survivors, there were significant adverse events noted in which 84 of the 95 had at least 1 associated adverse diagnosis reported; 37 of 84 respiratory conditions including arrest (44%), 16 of 84 had sepsis (19%), 11 of 84 had neurological harm (13%), and 8 of 84 had renal impairment (9.5%), 1 of 84 had hypersensitivity/hyper coagulopathy. Debora Simmons MSN., RN., CCRN.,

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<sup>3</sup> [Enteral feeding misconnections: a consortium position statement.](#)

Guenter P, Hicks RW, Simmons D, Crowley J, Joseph S, Croteau R, Gosnell C, Pratt NG, Vanderveen TW. *Jt Comm J Qual Patient Saf.* 2008 May;34(5):285-92, 245.

<sup>4</sup> National Health Service Public Safety Alerts. (n.d.). Promoting safer measurement and administration of liquid medicines via oral and other enteral routes. Retrieved from <https://webarchive.nationalarchives.gov.uk/20151105115412/www.nrls.npsa.nhs.uk/resources/search-by-audience/clinical-risk-managers/?entryid45=59808&cord=ASC&p=6&char=0-9>

<sup>5</sup> WHO Collaborating Centre for Patient Safety Solutions. (2007, May). Avoiding Catheter and Tubing Misconnections. Retrieved from <https://www.who.int/patientsafety/solutions/patientsafety/PS-Solution7.pdf>

<sup>6</sup> The U.S. FDA Center for Drug Evaluation and Research. (2018, October 10). Information for Consumers (Drugs) - Working to Reduce Medication Errors. Retrieved from <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143553.htm>

CCNS. (USP Safe Medication Use Expert Committee/Associate Director) states “Tubing misconnections have been on many patient safety organizations for over a decade. Though they are underreported, data shows the significant impacts of a tubing misconnections which is death or the need for long term critical care.” Healthcare safety professionals have realized that underreporting and non-detection of errors in healthcare are barriers to recognizing threats to patient safety on a national and institutional level.<sup>6,7</sup> Unfortunately, the healthcare industry relies on reporting systems to acquire safety data, which poses a challenge as some errors are not detected. A recent increase in the awareness of the scale of misconnection underreporting has caused widespread agreement among governmental agencies, professional organizations, and patient safety groups that this is a problem that needs to be addressed.

Peggi Guenter, PhD, RN, FAAN, FASPEN from the American Society for Parenteral and Enteral Nutrition demonstrated there are significant healthcare expenses associated with complications caused by misconnections. Guenter looked at all the misconnection incidents published in the Simmon *et al* review and evaluated costs for: death in hospital, respiratory insufficiency, sepsis and neurological disease. According to Agency for Healthcare Research and Quality (AHRQ), the estimated costs of hospital stays for patients who die in the hospital are upwards of \$20 billion. The difference between the cost of hospital stays in patients leaving the hospitals vs. those that die in the facility was almost triple (\$23,035 vs. \$9,447, healthcare only<sup>7</sup>). In cases where misconnections contribute to death, the increased costs, not including human suffering and lost productivity, can be calculated. While not all these costs are related to misconnections, the implications are that misconnections can contribute to costly healthcare bills and the incalculable loss of life. These issues can and should be avoided with the use of the new ISO 80369-3 standard.

A separate research-based organization, ECRI, included “Mix-Up of IV Lines Leading to Misadministration of Drugs and Solutions” in the top 10 technology hazards of 2015 and recommended to purchase only ISO 80369-1 compliant products<sup>8</sup>. ECRI recently followed up with two guidance documents that support the introduction of safer connectors in the healthcare community and reference ENFit as the solution “Implementing the ENFit Initiative for Preventing Enteral Tubing Misconnections” and “Critical Notice—Avoid Fatal Misconnections with ENFit-compliant Feeding Tube Connectors”<sup>9</sup>. In its most recent hazard communication about misconnections, ECRI emphasizes adoption of safer connectors. The article states “ECRI Institute and other organizations recommend that healthcare providers throughout the world transition to enteral devices with ENFit connectors as soon as practicable”<sup>10</sup>. These supporting

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<sup>7</sup> Zhao, Y., and Encinosa, W. The Cost of End-of-Life Hospitalizations, 2007. HCUP Statistical Brief #81. November 2009, revised April 2010. Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.hcup-us.ahrq.gov/reports/statbriefs/sb81.pdf>

<sup>8</sup> ECRI Institute. (2014, November). Top 10 Health Technology Hazards for 2015. Retrieved from [https://www.ecri.org/Resources/Whitepapers\\_and\\_reports/Top\\_Ten\\_Technology\\_Hazards\\_2015.pdf](https://www.ecri.org/Resources/Whitepapers_and_reports/Top_Ten_Technology_Hazards_2015.pdf)

<sup>9</sup> ECRI Institute. (2017, March 29). Implementing the ENFit Initiative for Preventing Enteral Tubing Misconnections. Retrieved from <https://www.ecri.org/components/HDJournal/Pages/ENFit-for-Preventing-Enteral-Tubing-Misconnections.aspx>

<sup>10</sup> ECRI Institute. (2017). Top 10 Health Technology Hazards for 2018. Retrieved from [https://www.ecri.org/Resources/Whitepapers\\_and\\_reports/Haz\\_18.pdf](https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_18.pdf)

documents also align with past articles from other regulatory bodies such as The U.S. Food and Drug Administration and The Joint Commission.

Two key and influential regulatory bodies acknowledged and gave visibility to the severe impact of tubing misconnections. The Joint Commission published a “Sentinel Event Alert, Issue 36: Tubing misconnections- a persistent and potentially deadly occurrence” in April 2006<sup>11</sup>. In addition to Sentinel Event 36, the Joint Commission issued “Sentinel Event Alert, Issue 53: Managing risk during transition to new ISO tubing connector standards” recognizing a new safer system was being introduced in the US market<sup>12</sup>. In line with the Joint Commission efforts in January 2009, the U.S. FDA published a medical device safety calendar depicting the adverse event case studies involving misconnections. In 2010 the U.S. FDA sent a letter to manufacturers of enteral feeding tubes, healthcare professionals and hospital purchasing departments, advising these groups of the dangers of misconnections and informing them of actions being taken to lower the risk<sup>13</sup>. Following the U.S. FDA’s awareness efforts in 2009 and 2010, it then published in 2015, “Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications,” recognizing ISO 80369-3 connectors as the solution to reduce the risk of enteral device misconnections<sup>14</sup>. Most recently in 2018, the FDA wrote a letter to healthcare providers, recommending hospitals and clinicians to use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standards, commonly known as ENFit. The letter was titled, “The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury”<sup>15</sup>.

### **Tubing Disconnections**

While there are numerous efforts in place to raise awareness and address tubing misconnections, there have also been significant ongoing concerns over tubing disconnections, which are often experienced by patients and caregivers in hospitals, skilled nursing facilities, and at home. An unintended consequence of most current legacy feeding systems equipped with male

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<sup>11</sup> The Joint Commission. (2006, April 3). Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence. Retrieved from [https://www.jointcommission.org/sentinel\\_event\\_alert\\_issue\\_36\\_tubing\\_misconnections—a\\_persistent\\_and\\_potentially\\_deadly\\_occurrence/](https://www.jointcommission.org/sentinel_event_alert_issue_36_tubing_misconnections—a_persistent_and_potentially_deadly_occurrence/)

<sup>12</sup> The Joint Commission. (2014, August 20). Sentinel Event Alert 53: Managing risk during transition to new ISO tubing connector standards. Retrieved from [https://www.jointcommission.org/sea\\_issue\\_53/](https://www.jointcommission.org/sea_issue_53/)

<sup>13</sup> The U.S. Food and Drug Administration. (2010, July 9) Retrieved from <https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf>

<sup>14</sup> The U.S. Food and Drug Administration. (2015, February 11). Safety Considerations to Mitigate the Risks of Misconnections with Smallbore Connectors Intended for Enteral Applications. Retrieved from <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313385.pdf>

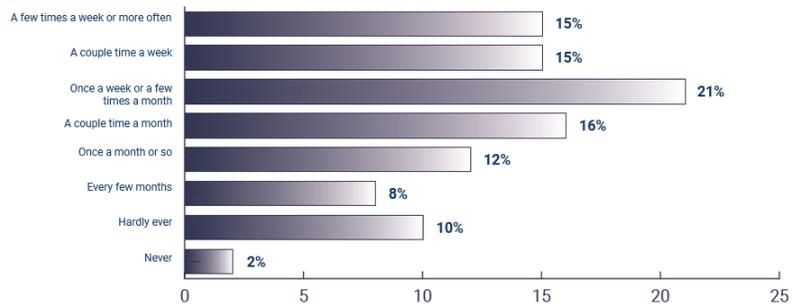
<sup>15</sup> The U.S. Food and Drug Administration. (2018, September 7). The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury. Retrieved from <https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM619782.pdf>

“stepped” connectors which couple with a friction fit into female feeding tube ports, is that a slight tug or snag can easily dislodge the connectors. Concerns with disconnections stem from loss of nutrition, water and medication leaking out, which is commonly referred to as “feeding the bed”. These disconnections have been associated with hospital visits and decreased quality of care for patients. This recurring issue is prevalent amongst tube feeders around the world. In efforts to find out the prevalence of tubing disconnections, The Feeding Tube Awareness

Foundation conducted an online survey in August 2017<sup>16</sup>, over a four-day period with 1,007 respondents. Results concluded the following:

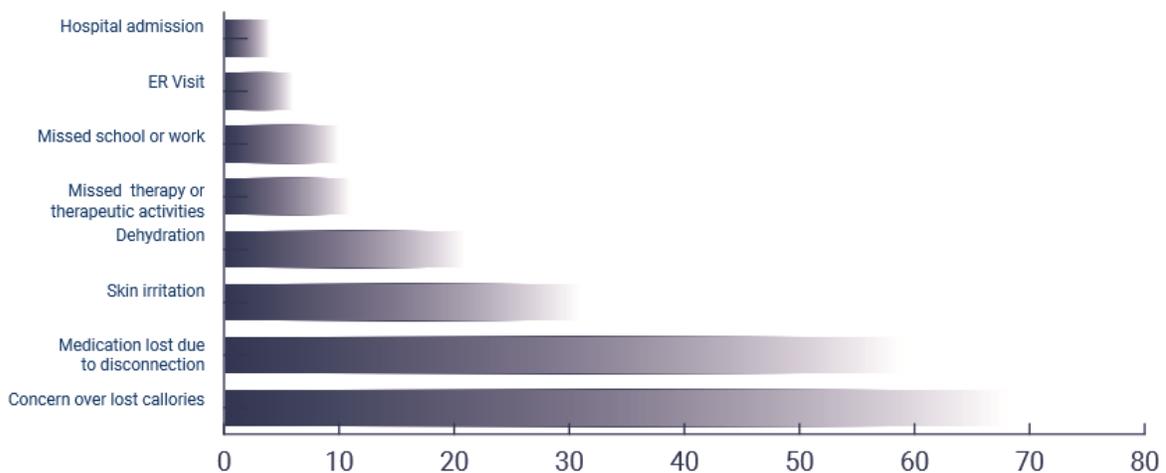
According to the survey, disconnections happen universally. The overwhelming majority, 98% of respondents have experienced a disconnection. In fact, 52% have experienced at least one disconnection per month while 20% of respondents experienced 100 or more disconnections since initial tube feeding.

How often do you experience tube feeding disconnections? By disconnections we mean that the tubing disconnects or the medication (med) port opens resulting in feeding the bed, chair, ect. and missed feeds



Like misconnections, disconnections are a cause for concern and may lead to unintended consequences, harmful events and/or hospitalization. 71% of respondents are very or somewhat concerned about disconnections because of the following consequences occurred from disconnections:

If you have had the experienced disconnections, has it ever resulted in any of the following? (Select all that apply)



While all of these consequences are concerning, 10% of the patients requiring a hospital visit is perhaps the most troublesome finding. Especially when considered in light of Center Medicare

<sup>16</sup> Feeding Tube Awareness Foundation survey of 534 parents, caregivers and tube feeders conducted in June 2-5, 2017. The data for this survey was collected using SurveyMonkey.com.

and Medicaid's quality directives to reduce hospital visit and readmission rates. These findings further substantiate the need for a new single, safer system for enteral feeding patients with the goal of reducing disconnections.

### **Actions Initiated to Address Misconnections**

There were three pivotal events that set in motion initiatives to address misconnections. First the Joint Working Group 4, (JWG4), originally co-chaired by Dave Johnson (formerly Halyard Health at the time) and Brad Noe (Becton Dickinson) was formed in 2008 to initiate the project for the ISO 80369-3 enteral device standard. Second, in 2013, the Global Enteral Device Supplier Association, commonly called GEDSA, was formed as a global communication and resource-based organization to help introduce the new connectors with a coordinated plan/voice into the healthcare community. The third pivotal event was the US State of California's legislation, AB444, enacted in 2014, that prohibits the compatibility of connectors among IV, epidural and enteral application<sup>17</sup>s.

### **Creation of ENFit**

The ISO 80369 standard series were created to reduce the risk of tubing misconnections among enteral, intravascular, epidural, and other therapeutic connectors. ISO 80369-1 specifies requirements<sup>18</sup> for the system-specific series of connectors, which are:

- Not connectable with others in series,
- Rigid or semi-rigid,
- Passes misconnection, risk analysis, usability/human factor testing,
- Not connectable with Luer or needleless connector ports.

Within the standard series, ISO 80369-3 is specific for enteral applications and specifies dimensional requirements for enteral connectors. The ISO 80369 series of standards consist of sub parts which detail general requirements for small bore connectors in healthcare applications (ISO 80369-1) and requirements for small bore connectors for specific healthcare applications ISO 80369-3, ISO 80369-5, and ISO 80369-6). ISO 80369-1 was published in 2010. ISO 80369-3 was published in 2016. A connector which complies with ISO 80369-3 by default complies with ISO 80369-1. However, a connector which complies with ISO 80369-1 does not always comply with ISO 80369-3. This can be confusing but can be understood better by the intent of each standard. ISO 80369-1 defines universal requirements that all small bore connectors for healthcare applications need to meet in order to reduce the risk of misconnections only. ISO 80369-3 defines dimensional requirements to ensure incompatibility with other systems of small bore connectors and functional requirements to ensure the 2 enteral connector halves are compatible. Therefore, a connector could comply with all of the requirements of ISO

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<sup>17</sup> AB-444 Cal. Adv. Legis. Serv. (LexisNexis). Retrieved from [http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\\_id=201520160AB444](http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160AB444)

<sup>18</sup> ISO 80369-1:2010, Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements. Retrieved from <https://www.iso.org/obp/ui/#iso:std:iso:80369:-3:ed-1:v1:en>

80369-1 but not comply with the requirements, dimensional and/or functional, of ISO 80369-3. The ISO 80369-1 standard series was recognized globally as an official standard in 2014.

During the development of ISO 80369-3, ISO JWG4 considered two patient access connector designs previously developed by two European companies. Both designs were evaluated for misconnection risk and usability. However, both designs were ruled out due to unacceptable major misconnection risks and/or usability issues without possible design modifications. JWG4 began work to define new design options for enteral connectors. The initial design, combined the two best aspects of the proposed systems from the European companies. PGLock was the internal working project name for what is known today as the ISO 80369-3 (ENFit) connector.

During the creation of ENFit, there were a number of factors to consider. The main issue revolved around creating a design suitable for all patient populations and regions. Once the design was identified, then the direction of flow for the connectors was debated. At the time, due to the relative success of the enteral feeding system adopted in the United Kingdom for over a decade and the decreased misconnection risks associated with placing the male connector on the patient side, technical, clinical and regulatory experts insisted that any new design changes must be introduced with flow in the same orientation as the UK reverse Luer lock system. Therefore, the ENFit connector configuration is oriented with the flow from the female (administration set and syringes) to the male (feeding tube) thus allowing for a physical cue unique to enteral devices. This orientation limits the ability to insert common male connectors into a female port. ENFit connectors are compliant with the ISO 80369-3 standard while utilizing the female to male direction of flow. The ENFit design has since been adopted by the vast majority of the enteral device manufacturers.



### **Creation of GEDSA**

The Global Enteral Device Supplier Association (GEDSA) is a globally oriented non-profit trade association established to help introduce the new ISO standard connector and facilitate adoption of the ENFit connectors in the healthcare community. GEDSA is comprised of leading manufacturers, distributors and suppliers of enteral nutritional devices, united by a shared goal to improve patient safety and optimal delivery of enteral feeds and medications.

GEDSA speaks with a singular industry voice to communicate with governing agencies, patient safety organizations, end users/patients, hospitals, health systems and member suppliers, regarding issues that face enteral device manufacturers, suppliers and distributors. GEDSA leads a joint communication effort on behalf of the industry to ensure consistency and avoid confusion as new, safer connectors are introduced around the world.

As GEDSA was established in 2013 and word circulated about its mission and purpose, membership grew. Today GEDSA is made up of over 30 companies from around the globe. In addition to the members, GEDSA has gained support from a number of clinical and regulatory organizations such as [Institute for Safe Medication Practices \(ISMP\)](#), [Economic Cycle Research Institute \(ECRI\)](#), [The Joint Commission](#), [American Society of Health-System Pharmacists \(ASHP\)](#), and [American Society for Parenteral and Enteral Nutrition \(ASPEN\)](#) and many others.

### **Legislation**

California law AB818 (later modified and renamed AB444) was enacted with a targeted enforcement date of January 1, 2014 or 36 months after the publication of the new design standard, whichever comes first. Since its initiation, AB444 was amended in March 2013 to prohibit health facilities from using IV, epidural and enteral device connectors which would connect with unrelated systems. The enforcement date later shifted to January 1, 2016. In August of 2015, California AB444 was approved by the Governor of California and amended to section 1270.7 of the Health and Safety code, which extended the enforcement date to July 1, 2016 for enteral connectors and January 1, 2017 for epidural connectors.

### **Global Introduction**

Introducing ENFit to the healthcare industry has been an ongoing challenge. Market feedback shows high adoption rates outside the US, with several countries nearly fully transitioned including the UK, Netherlands, France, Ireland, Italy, Australia, and New Zealand. However, ENFit adoption in the US remains stagnant since it has not yet been mandated by any regulatory body outside of the state of California. To aid adoption throughout the globe, GEDSA facilitates information flow through a four phase initiative: *Aware, Prepare, Adopt, and Measure*<sup>™</sup> which is designed to increase patient safety and optimal delivery of enteral feeds and medications. The goal of this strategy is to ensure that all stakeholders have the necessary tools and information to implement the change with minimal issues and maximum benefits. GEDSA collects best practices and tools from its membership's experience with successful conversions internationally and domestically, then broadly disseminates this knowledge to help accelerate the adoption of the safer ENFit connectors.

#### **Aware:**

In order to accelerate ENFit adoption, it is crucial to build awareness across facilities, throughout the supply chain and among providers; including all affected clinicians, administrators and support staff. To drive awareness effectively, a strong communication

foundation was established to address the fundamental questions: Who, What, Where, When, Why & How. The tools that GEDSA, its affiliated clinicians and associated entities have developed, include thorough, user tested education materials and support tools to educate healthcare facilities and end users.

Educating the market and all its stake holders on ENFit has been challenging given the different delays in transition. However, more than three-quarters of respondents are very, or at least somewhat familiar with ENFit; according to a recent awareness study conducted by the Feeding Tube Awareness Foundation. The study findings suggest that respondents are not only well aware, but they are eagerly awaiting this change. The Feeding Tube Awareness Foundation conducted a study in

August 2017 to test the familiarity and responses to the transition ENFit. The study’s results concluded the following:

How familiar are you with ENFit?

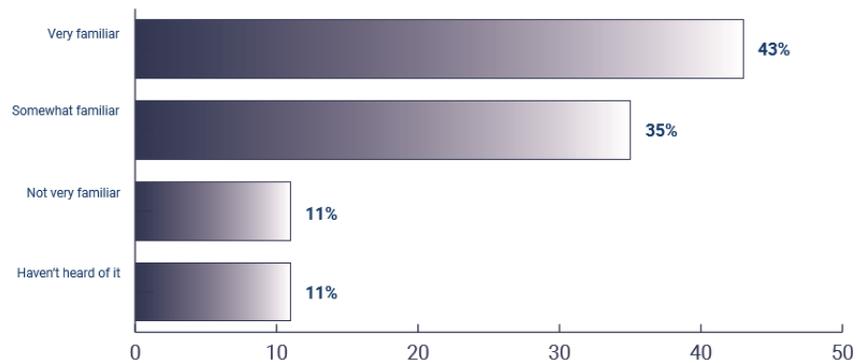


Figure 6

The results of this study demonstrate a strong level of awareness (78%) for ENFit, but unfortunately those high levels have not resulted in mass adoption in the US, unlike other regions.

**Prepare:**

The Readiness stage is comprised of several important tactics that touch on all parts of the healthcare system and the associated caregivers and stakeholders who administer enteral feeds and medications. Global manufacturers worked on product development/specifications, sourcing and management of inventory (old and new product, co-storage of stock keeping units) to support the healthcare community with the transition. Especially important in the process is managing expectations and fulfillment to distributors and their clients. This has proven to be a challenging step.

Numerous articles have been published by supporting organizations, with hopes of bringing increased awareness and preparation for a full ENFit adoption. The following articles, support the need for ENFit:

1. **The Centers for Medicare and Medicaid Services (CMS)** released a statement on October 4<sup>th</sup>, 2018 about “[Enteral Device Connectors that Reduce Patient Injury](#)” referencing the recent FDA letter.
2. **The U.S. Food and Drug Administration (FDA)** wrote a letter to healthcare providers to “[Encourage Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury](#)”. The letter was published on September 7<sup>th</sup>, 2018.
3. **Economic Cycle Research Institute (ECRI)** released “[Critical Notice–Avoid Fatal Misconnections with ENFit-compliant Feeding Tube Connectors](#)” on March 29<sup>th</sup>, 2017.
4. **American Journal of Health-System Pharmacy (ASHP)** published “[Transition to ENFit enteral devices: Special challenges for pediatric institutions](#)” in November 2016.
5. **British Association for Parenteral and Enteral Nutrition (BAPEN)** published “[ISO 80369-3: IMPORTANT UPDATE – ENFit Implementation](#)” in October 2016.
6. **The U.S. Food and Drug Administration (FDA)** published a guidance on “[Safety Considerations to Mitigate the Risks of Misconnections with Small Bore Connectors Intended for Enteral Applications](#)”. This document was issued on February 11, 2015. The draft of this document was issued on July 27, 2012.
7. **Institute for Safe Medication Practices (ISMP)** published Medication Safety Alert “[ENFit Enteral Devices are on their way... Important safety considerations for hospitals](#)” on April 9<sup>th</sup>, 2015.
8. **National Health Services (NHS)** published a patient safety alert “[Stage One: Warning – Managing risks during the transition period to new ISO connectors for medical devices](#)” on March 27<sup>th</sup>, 2015.
9. **The Joint Commission** revised Issue 36, thus Sentinel Event Alert 53 called: [Managing risk during transition to new ISO tubing connector standards](#) was created on August 20<sup>th</sup>, 2014. The document touches more on the adverse events and making people aware of the deadly repercussions of tubing misconnections.
10. **American Society for Parenteral and Enteral Nutrition (ASPEN)** published “[A.S.P.E.N. Supports Major Medical Device Changes for Improved Patient Safety](#)” on October 22<sup>nd</sup>, 2013.
11. **Center for Medicare & Medicaid Service (CMS)** addressed State Survey Agency Directors on “[Luer Misconnection Adverse Events](#)” on March 8<sup>th</sup>, 2013.
12. **Association for the Advancement of Medical Instrumentation (AAMI)** published “[ISO 80369-1 Small bore connectors for liquids and gases applications](#)” in January 2010 and is recognized by the U.S. FDA.

GEDSA continues to support the initiative of patient safety around the world. To advance its mission, GEDSA continues to hold conferences, webinars and regional summits to help prepare

healthcare facilities for the transition to ENFit. Additionally, GEDSA has provided the website [www.StayConnected.org](http://www.StayConnected.org) as a hub for ENFit information and resources.

**GEDSA Support to Prepare for ENFit Transition**

<p style="text-align: center;"><b>Research &amp; Studies</b></p> <ul style="list-style-type: none"> <li>• FDA &amp; Mayo Clinic Blenderized Diets Tests and Results</li> <li>• Disconnections Survey and Results</li> <li>• Dose accuracy protocol and 3<sup>rd</sup> party testing</li> <li>• Dose Accuracy Research Poster</li> <li>• ENFit Adoption Survey and Results</li> <li>• Cleaning Study and Protocol/Guidance</li> </ul>	<p style="text-align: center;"><b>Education</b></p> <ul style="list-style-type: none"> <li>• Hospital ENFit Implementation Success Stories</li> <li>• Transition Checklists</li> <li>• Inpatient and Outpatient Medication Administration Educational Videos &amp; Infographics Poster</li> <li>• StayConnected Newsletters: most current ENFit information</li> <li>• StayConnected Website</li> </ul>
<p style="text-align: center;"><b>Guidelines: Facilitating ENFit Implementation</b></p> <ul style="list-style-type: none"> <li>• Inpatient and Outpatient Medication Administration Infographics</li> <li>• Guidance on Adoption of ISO 80369-3</li> <li>• ENFit Implementation Team Guideline</li> <li>• Facility In-Service Presentation</li> </ul>	<p style="text-align: center;"><b>Advocacy &amp; Awareness</b></p> <ul style="list-style-type: none"> <li>• National Summit: Children’s Hospital of Los Angeles</li> <li>• Regional Summits: California, Indianapolis, Missouri, Illinois, Wisconsin, North Carolina, and Ohio</li> <li>• ENFit Webinars hosted by GEDSA and available on demand</li> <li>• ENFit Adoption Petition</li> </ul>

**Adopt:**

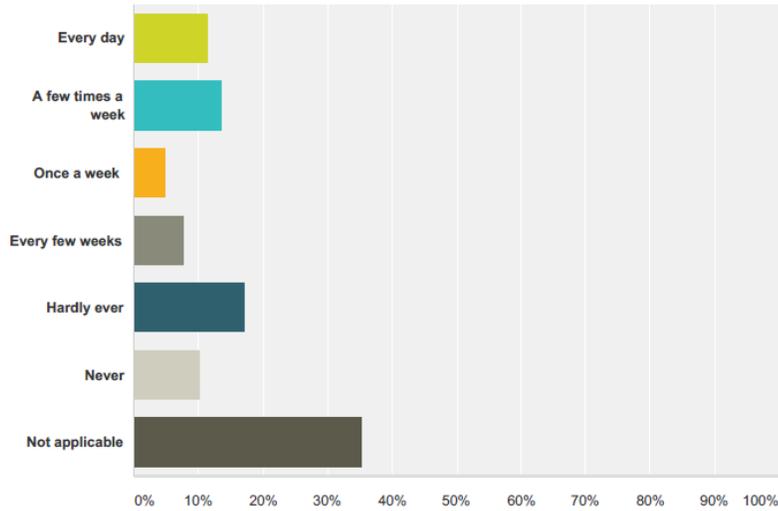
To introduce new connectors into a healthcare workflow, it is critical to create adoption milestones and follow a plan for all stakeholders; from end users to manufacturers and distributors. By this stage, the cross-functional teams should have set a “go-live” date for the facility and have completed all the training necessary for the adoption phase. During the adoption phase, hospitals and healthcare facilities should be implementing ENFit while understanding best practices or areas they can improve upon for the next ISO 80369 standard series introduction.

It is important to note that healthcare providers, patients, and caregivers are currently in a suboptimal position with the ENFit adoption. Initial transition connectors were only intended to be a temporary bridge to manage patients with tubes meant to be in place for an extended period of time or provide care for a patient who has not yet transitioned to the new connectors. With the current slow rate of adoption, transition connectors have been utilized for over three years. Concerns regarding the transition connectors have been reported to GEDSA. Another common issue with the transition connectors comes from the lack of a standard design amongst legacy funnel connections that can result in suboptimal connections to the legacy funnel style tubes.

Specific details are shown below from a survey conducted by the Feeding Tube Awareness Foundation:

**Q3 If you are using ENFit transition adapters, how often have you had problems with them?**

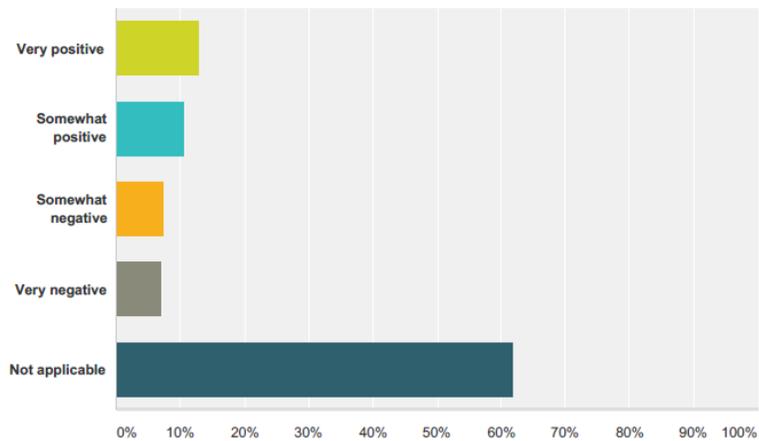
Answered: 523 Skipped: 11



The survey determined that utilizing all ENFit components (ENFit to ENFit) is superior to using

**Q4 If you are using ENFit to ENFit connections, what has your experience been?**

Answered: 517 Skipped: 17



transition connectors. More than two-thirds of respondents report a favorable experience with their ENFit to ENFit connections. Importantly, 59% of these responses are from outside the U.S., where adoption is significantly more complete.

Although ENFit offers great experiences for most respondents, the negative survey answers expose less positive experiences that are directly attributable to the lack of ENFit supplies.

Q: Please explain any problems that have occurred when using ENFit.

- *“We love ENFit to ENFit. My only problem is we are not consistently getting the ENFit supplies from the DME.”*

- *“Unfortunately, our supplier has stopped sending us those type of extensions now.”*

- *“Love it can’t wait to go totally ENFit with the syringes.”*

- *“Although the ENFit connection itself is good, I cannot get a tube or adaptor with a second port for medications or flushes, so I need to disconnect multiple times during each feed.”*

These surveys demonstrate the clear value of ENFit adoption vs. transition tubing. However, to ensure positive outcomes, it is critical to prepare and secure support from manufacturers and distributors to meet the necessary demand.

### **Measure:**

Analyzing patient safety data remains a vital component in informing the enteral feeding community regarding hazards to safe care and creating preemptive approaches to patient safety. In this phase, it’s critical to demonstrate the cross-functional team’s ability to adopt changes and reassess how to improve the process for the next phase. To determine the effectiveness of the ENFit transition, it is important to have agreed upon measurements for all junctures in the adoption and post-adoption phases.

Clinical and technical experts from around the globe have joined together to test, vet and agree on ENFit as the best solution. Significant awareness has been achieved, per the study (78%). GEDSA has developed significant materials to Prepare stakeholders. The two final stages, Adopt and Measure, need a streamlined, universal protocol with clear timelines to enable full transition to the new single, safer ENFit connectors.

### **Transitioning Challenges and Solutions for Adoption**

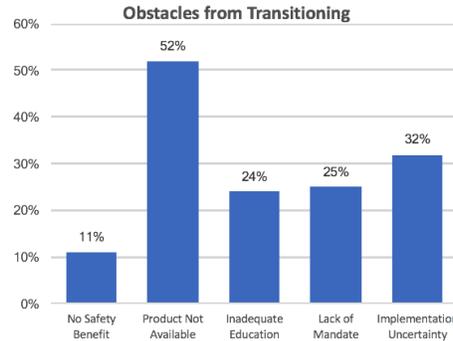
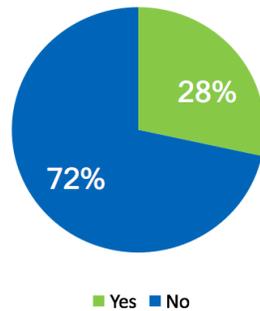
Since awareness efforts started in 2014, a number of concerns and obstacles to adopting ENFit have been raised. However, this should come as no surprise when magnitude of this paradigm shift in patient safety is considered. After all, it’s been close to 120 years since the Luer was introduced and these new dedicated connectors represent the first significant and standardized departure from that. With efforts from manufacturers, supporting organizations and experts, solutions have been identified. While ENFit has proven to be successful in reducing the risk of misconnections, several delays along the way have contributed to slow adoption; resulting

in an extended transition stage. With such widespread changes in healthcare, these types of concerns are to be expected and are important to address ahead of any full-scale adoption.

According to a recent ENFit adoption survey<sup>19</sup>, with over 500 respondents, the greatest barriers to transitioning were the following:

## ENFit Survey Results

Has your facility transitioned to ENFit?



While 89% of respondents do believe there is a safety benefit to ENFit, there continues to be resistance to change. Since early 2017, GEDSA has focused on removing the following four obstacles: education, implementation uncertainty, lack of mandatory regulation and supply concerns.

### Inadequate Education

GEDSA has prepared multiple educational tools and materials that are currently available on the portal *StayConnected.org*. These resources include materials that support the ENFit introduction and come in the form of webinars, toolkits, newsletters, FAQs, protocols, recommendations, informational videos and regional summits listed in Figure 7.

### Implementation Uncertainty

Initially there was uncertainty surrounding whether ENFit was a suitable solution to address tubing misconnections and disconnections because of questions regarding the performance of the new connectors. Over the past several years, GEDSA, with the help of its members’ technical experts, has taken the time to understand the following challenges:

### Flow Rates and Pressure

In 2014, shortly after GEDSA began its education effort on the ENFit connector system, home tube feeders and their caregivers began to raise concerns regarding the potential

<sup>19</sup> The data for this survey was collected using SurveyMonkey Inc. “ENFit Adoption Survey” (August 2018). <https://www.surveymonkey.com/r/ENFitAdoption>

impact the ISO 80369-3 standard connectors could have on the delivery of tube feeding.<sup>20</sup> To gain more information specific to these concerns, consumer and clinical listening sessions were conducted by whom, where and when. With the knowledge gained from these sessions, the Oley Foundation, U.S. Food and Drug Administration (FDA), Mayo Clinic, Feeding Tube Awareness Foundation (FTAF), GEDSA and other subject matter experts, formed a task force to understand the potential implications of the new ENFit feeding system. The objective of this task force was to assess the possible impact of the new ENFit connector system on the performance of delivery system components (specifically syringes, feeding tubes, feeding sets, and connecting tubing) when using homemade blenderized diets and commercial tube feeding formulas through rigorous scientific study.

Researchers at the Mayo Clinic Rochester and the U.S. FDA's Center for Devices and Radiological Health conducted research comparing the performance of the legacy feeding tube systems as compared to ENFit connector systems<sup>21</sup>. The two sites used similar protocols to measure flow rates and delivery force of products with the legacy funnel style connecting system as compared to products equipped with the ENFit connection. Both the Mayo Clinic and the FDA found similar results in the flow testing. In general, the flow rates and gravity flow rates of the legacy system and the ENFit system were largely similar. The study showed the most critical factor affecting flow rates in homemade blenderized tube feeding was the size of the particulate in the formula, the type of blender used and the duration of blending time. When comparing products with the legacy funnel connecting systems to those with ENFit connectors, it was shown that syringe plunger force levels for both systems were similar at both sites. Statistical analysis by researchers at the Mayo Clinic showed that tube diameter, blender type, and blending time had a greater impact on force levels than the change in the connector system. The U.S. FDA concluded that products with ENFit connectors required the same or less force than products with legacy connectors. In a separate study, the U.S. FDA tested patient blenderized diets, under gravity and push mode feeding, through five legacy G-tube brands and three corresponding ENFit brands (sized between 14 Fr and 24 Fr). The results concluded that patients using push mode "will largely be impacted after the transition to ENFit. For a gravity mode of feeding, some ENFit users may need higher-powered blenders and should expect increased feeding times."<sup>22</sup> Thanks to the research by the Mayo Clinic and FDA we have, for the first time, a more clearly documented understanding of ENFit's impact on enteral delivery systems.

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<sup>20</sup> The ISO 80369 small bore tubing connector standard series was developed to prevent potentially deadly medical device tubing misconnections, the first series being introduced around the world, ISO 80369-3, is specific to enteral feeding.

<sup>21</sup> Mundi, M. S., Duellman, W., Epp, L., Davidson, J., & Hurt, R. T. (2018). Comparison of Gravity Flow Rates Between ENFit and Legacy Feeding Tubes. *Journal of Parenteral and Enteral Nutrition*, 42(3), 522-528. <https://doi.org/10.1177/0148607117703959>

<sup>22</sup> Suvajyoti Guha, Nesrine Bouhrira, Mark J. Antonino, Joshua S. Silverstein, Jeffrey Cooper & Matthew R. Myers (2019) Impact of Design Changes in Gastrostomy Tube (G-tube) Devices for Patients Who Rely on Home-Based Blenderized Diets for Enteral Nutrition, *Journal of the American College of Nutrition*, DOI: 10.1080/07315724.2018.1509247

### **Dose Accuracy**

Clinicians raised concerns about the dosing accuracy of small volume ENFit syringes due to their reverse gender orientation. These clinicians expected a dosing accuracy of  $\pm 10\%$  for a target volume of 0.2mL when delivered from a 1mL syringe. At the time, there was no global standardized test nor any baseline data to determine dose accuracy. Performance testing was then conducted by a third-party, to determine the performance of legacy and ENFit systems. The following enteral syringe types were evaluated to determine their dose accuracy performance in order to establish a baseline for the performance of existing syringes and to test the proposed LDT syringe: Three leading brands of existing enteral/oral syringes (all male tip), female Luer lock (reverse system used in the UK), a proprietary reverse system syringe currently marketed, standard ENFit syringe tip, and the proposed ENFit low dose tip syringe.

The study established and confirmed the accuracy of the ENFit syringe. The researchers showed that in order to obtain the desired dose accuracy, manufacturers of ENFit Low Dose Tip (LDT) syringes should specify in their instructions for use and labeling, commonly called IFUs, that syringe users should remove any fluid that lies outside of the fluid path. The area between the male lumen and the outer ring (called the “moat”) is not part of the fluid path and should be free of fluid. In settings that require highly accurate low volume doses, an ENFit LDT Syringe satisfies the performance expectations for dose accuracy, dead space, and tolerance on graduated capacity; there is no significant difference between use of ENFit LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (pharmacists, nurses, or caregivers).

Syringes are commonly used in enteral feeding for hydration, flushing, bolus feeds and for administering medication. Feeding tubes and medication ports on feeding sets with new ENFit male connectors will require new ENFit tip syringes. ENFit tip syringes are appropriate for use in all healthcare settings for flushing, hydration, bolus feed and administering medication enterally. However, for precise dosing, auxiliary devices such as draw-up straws or fill caps may be necessary.

### **Cleaning**

Concerns were raised regarding cleaning protocols for the threads around the male ENFit connector. In response GEDSA formed a technical team led by Beth Lyman MSN, RN, CNSC from Children’s Mercy Hospital Kansas City and Dr. Peggi Guenter, PhD, RN, CNSN, from ASPEN to develop and validate a procedure. The team first created a three-phase lab study with ENFit connectors, multiple test soils in the moat of the connector, and several different types of cleaning utensils (brushes) with water. The specific aim of this study was to evaluate the efficacy of a cleaning protocol for ENFit connectors by:

- Visible evaluation of the cleaning procedure before and after cleaning, using a nominal scale to score the effectiveness of the cleaning procedure.

- Evaluation of the cleaning procedure after application of a gel UV marker as a test soil and then using a black light and nominal scale to score the effectiveness of the cleaning

Based on the study results, a protocol was designed, reviewed and submitted to the Biosafety Committee and IRB at Children’s Mercy Hospital in Kansas City, Missouri for final approval. The procedure was not incrementally complicated versus the standard Luer lock cleaning protocol. [{Details of the cleaning protocol are available at \*StayConnected.org\*}](#)

## Marketplace Dynamics

### Legacy Enteral Device Market

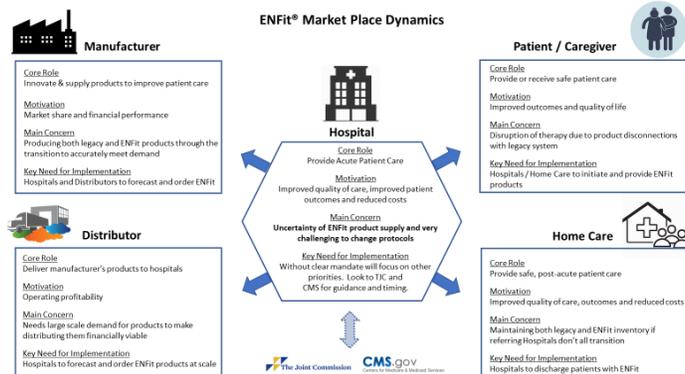
In the current enteral device marketplace, tube feeding product demand is driven by the number of patients cared for by the health system providers (hospitals, home health, pharmacies, etc.) and the supply provided by manufactures and suppliers competing through national and regional distributors for market share. As a mature market, the current enteral device marketplace is also a relatively predictable market because patient need for tube feeding products is largely based on population trends established over several years. Because of this characteristic, hospitals, distributors and manufacturers have developed ordering, production and delivery schedules that help ensure products are available for patients when needed, and that the costs (such as raw material sourcing, inventory management transportation, etc.) associated with doing so remain manageable.

The health systems are motivated by the Triple Aim of providing quality of care, improving patient outcomes and reducing costs. Suppliers and manufacturers, who are motivated by improving financial performance, are pleased when they are meeting their standing goal to forecast the supply and demand of products accurately. However, when faced with the opportunity to advance patient care, as is the case with ENFit, manufacturers face some difficulties in overcoming this legacy market efficiency.

### ENFit Adoption Stagnation

Healthcare providers, distributors and manufacturers have a shared mutual interest in advancing patient care through the adoption of ENFit. However, implementation is largely at a standstill due to competing priorities, perceived risks to continuity of patient care, and suppliers and manufacturers’ cost concerns of serving an underdeveloped marketplace.

When looking at the ENFit market from a supply perspective, manufacturers have been working for several years to design and produce products that meet the ISO standards. Guided by self-imposed GEDSA timelines, manufactures and suppliers have now collectively reached



critical mass in the supply of ENFit products and are ready to meet the healthcare providers' needs for adoption of ENFit globally. This critical mass of inventory resides in their respective warehouses, and once orders are placed, the initial supply of products will be available to distributors within 4-8 weeks, depending on location and logistics involved. Once the pipeline shipments are in place across the healthcare system and demand is properly forecasted with enough lead time, future ordering, production and delivery schedules should revert to what was observed with the previous legacy products. However, since demand is not dramatically increasing, supply remains somewhat stagnant.

From a distributor's perspective, the ENFit market is underdeveloped and unattractive given the low adoption and order rates. Distributors' business model becomes favorable when they are providing products to the health care system in high volumes. While there may be a large number of hospitals that have not yet adopted, the product volumes of the few won't justify a distributor's minimum order quantities from manufacturers. In addition, the inventory costs associated with supplying the products is not financially viable. As such, until distributors have volume estimates and can order on a large scale or they are confidently able to displace the corresponding legacy item in their warehouses, they are unwilling to secure products from the manufacturers or make ordering them an option to the hospital system.

The critical partner in adoption is the health care system, as they initiate tube feeding with the patient while under their care in a hospital setting. While individual manufacturers may have incomplete product portfolios, collectively all products are available from manufacturers as a group. Distributors are able to access this supply but may not be doing so until more significant demand exists. Hospital systems tend to rely more heavily on their distributor partners than the manufacturers directly, thus their perception may be that supply is not readily available. Communication of anticipated "Go-live" dates, setting a demand forecast, and educating the healthcare community within each facility does take considerable time, careful communication, coordination, and assertiveness to execute in a timely fashion.

GEDSA has heard repeatedly from hospital systems that a full-scale conversion is daunting. While GEDSA recently developed numerous materials, checklists and how-to guides, the overriding conclusion most facilities reach is to wait on this initiative until they are told by some authority that conversion is mandated. Take California as a prime example, the only state in the US, effective July 1, 2016, that has established legislation (CA AB444) mandating hospitals to adopt a safer connector system. While the law does not specify ENFit but instead points to the ISO standard, ENFit connectors are the only product widely available today which meet the ISO standard. Despite California's legislation, low adoption rates are widely reported and it is estimated by industry that only 22% of hospitals in California have fully converted, more than one year after the legislative deadline. The reason adoption is not at or near 100% in CA is because there is currently zero enforcement of the legislation by any state agency or regulator.

The marketplace faces a situation of adoption that can only be broken through an enforced mandate from a state or federal agency that compels hospitals to adopt ENFit on a large scale with an established timeline. All stakeholders require adequate planning to adopt ENFit without disruption to patient care and in a cost-efficient manner. Creating a directive would be the most expedient way for the market to achieve a balance in demand and supply and eventually operate as efficiently as the current legacy market.

## **1. Lack of Regulatory Mandate**

GEDSA is advocating for a regulation within the US to push for market adoption of ENFit for a single safer system. GEDSA believes, based on the observed success in the UK, that regulatory intervention would expedite the adoption of the new ENFit standard. With the collective support of the United Kingdom's National Health Service (NHS), the enteral device supplier industry, and select clinical advisors, all aligned to the full-scale adoption of ENFit on an a specific timeline - the UK has achieved ENFit adoption rates over 95% with no reported misconnections, dosing concerns, or major transition problems. The NHS took the lead in setting a timeline that was then communicated by supporting organizations and manufacturers to avoid market confusion and increase patient safety throughout the country.

In other parts of Europe, Australia, and New Zealand, adoption rates are estimated at well over 50% with no reported events or product performance concerns. The US adoption rates are currently lagging behind because there is no mandate for change or enforceable deadlines for adoption. Many hospitals are hesitant to begin the final stage of ENFit adoption and a mandate would ensure all critical stakeholders are committed, aligned and will execute the final transition phase on schedule.

## **Concluding Recommendations:**

Clinicians, regulators, and industry have been working for more than 10 years to identify, develop and address all relevant concerns from stakeholders to aid the transition to a single safer enteral feeding system to eliminate tubing misconnections and disconnections worldwide. In order to finalize the ENFit adoption, GEDSA proposes a proactive, integrated approach amongst all key stakeholders.

### **1. Initiate a Mandate**

As much as regulatory bodies have given advice and encouragement, unfortunately there is still stagnation of ENFit adoption. After the last advocacy meeting held in Washington, DC on May 4, 2018, attendees realized and supported a mandate that would set the stalled adoption on the right path. The right path would include not just support but enforcement. Enforcement is critical from all regulatory bodies, but most importantly, Centers for Medicare and Medicaid Services (CMS). CMS is focused on six tenets of its Quality Improvement Roadmap (Safe, Effective, Efficient, Patient-Centric, Timely and Equitable), and has an appropriate role in establishing leadership in ENFit adoption. Further, its strategic goal of working in partnership and bringing solutions to

market more rapidly substantiates the need to issue guidance on the ISO 80639-3 standard (ENFit). The standard was developed with a focus on patient safety first and will drive both effective and efficient care for enteral feeding patients. This would have a dramatic impact on the overall ENFit adoption rates given its scale. With CMS establishing proper measurements and demonstrating success (fewer adverse events and re-admissions), more hospital systems would understand the importance and value of the ENFit initiative to CMS and its reimbursement policies.

2. Reissue Supporting Documents and Create Infrastructure

Upon receiving the most recent guidance from CMS and the FDA, it is recommended that the Joint Commission re-issue SE Alert #53 with stronger language, encouraging adoption that aligns with CMS's guidance. Additionally, TJC should prepare and train surveyors to evaluate ENFit adoption milestones and measures (formal survey and audit), thereby solidifying a commitment to change.

In partnership with CMS and TJC, the FDA can actively support the ENFit single safer system by establishing a firm deadline for the removal of legacy tubes and transition connectors from the market and accelerating the full adoption of ENFit. The FDA's instruction would include clear guidance on steps for hospitals and health care systems to follow and clarify specific reporting mechanisms to demonstrate compliance.

3. Ensure Compliance

Hospital systems, pharmacies, and home care facilities will begin to formally convert based on several factors: available supply of ENFit and a conversion deadline as activated by the FDA, TJC enforcement of milestones and deadlines by surveyors and CMS reimbursement standards are established.

The deployment of the ENFit feeding system creates an immediate patient safety benefit. Any delay in the introduction of ENFit continues to put patients at risk. It is GEDSA's mission to promote safe and optimal delivery of enteral feeds and medications and we strongly advocate the adoption of a regulatory mandate as soon as possible.

***About the Author***

This white paper was written by the GEDSA Communications Committee and Board of Directors.

The Global Enteral Device Supplier Association (GEDSA) is a 501(c)6 nonprofit trade association formed to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers of enteral nutrition devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections.

ENFit is a federally registered trademark of GEDSA in multiple jurisdictions throughout the world.

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