

ENFit® Adoption Action Plan

After capturing the feedback from stakeholders throughout the ENFit Adoption Summit, GEDSA has formalized an action plan. Supply was the number one reoccurring theme keeping hospitals and home infusion companies from transitioning. Other topics related to building confidence among all stakeholders through advocacy, better preparation, tools for adoption as well as proper maintenance of a new feeding tube with ENFit connectors were concerns that were also raised. Below is a brief summary of each bucket of challenges and the ‘task forces’ that will be assembled to address the concerns:

- **Demand Planning** - Establish a dialogue between manufacturers, distributors and end users to build a common forecasting tool to understand the needed product supply for a facility to transition. This will allow hospitals to set expectations for product and supply requirements needed to execute a careful transition.
- **Advocacy** - Drive initiatives to support easy access to ENFit syringes particularly for patients at home. Included in this bucket is addressing the challenges of Rx vs. OTC designation for medication syringes, awareness and availability at retail pharmacies. This task force will also assess the challenges with reimbursement of medication syringes.
- **Tools** - Create a master tool kit that can be used to train clinical staff for in patient use as well as preparing patients and caregivers at discharge for care at home.
- **FMEA (Failure Mode and Effects Analysis)** - Is a proactive tool, technique and quality method that enables the identification and prevention of process or product errors before they occur. This team lead by ASHP and ISMP will understand any potential failures and conduct a system reliability study for all to adopt and utilize within their own facility
- **Cleaning Protocol** – Determine clinically based best practices and protocols for cleaning ENFit connectors and keeping tubes patent over time. Included will be a microbial study to determine the best methods for cleaning to eliminate the build-up of bad bacteria harmful to the tube fed patient.

Each task force will have different objectives but overall the goal is to understand how we all impact supply and demand and how to collectively remove barriers to the adoption of ENFit. Below are the background and objectives of each task force.

Demand Task Force

Background: Adequate supply to meet growing demand of ENFit products is the responsibility of the manufacturers. Supply of a full system with multiple options of components to the healthcare facilities is up to the distributors. While the necessary components to begin the transition to ENFit are available from manufacturers, distributors are not bringing in supply of the new ENFit devices because there is still a high demand for legacy devices and low or no demand of ENFit. Both manufacturers and distributors are anxiously awaiting an increased demand for ENFit components. Sharing a demand forecast with your manufacturers and distributor partners along with your “go-live” date will trigger supply in the proper channels within supply chain. The communication between the manufacturer, supplier and end user is currently not in sync.

Objective: To understand how hospitals can set expectations of the exact products they will need from the distributors, for the distributors to then be able to request the right product from the manufacturers by the go-live date of the hospital. A key deliverable for this task force will be to establish forecasting tools as well as important conversations to review with your extended supply chain team.

Advocacy Task Force

Background: Access and availability of medication syringes is another issue hindering the adoption of ENFit. Today enteral/oral syringes used with legacy feeding tube are available over the counter and online. Two of the main challenges with access of ENFit syringes today are because of the FDA classification on enteral syringes. Unlike legacy products that are available over the counter, ENFit syringes require a prescription which inhibits the availability of ENFit syringes in other settings. In addition reimbursement has been a challenge another major challenge impeding the adoption of ENFit.

Objective: To ensure availability of ENFit syringes for all patients. This task force will drive initiatives to support easy access to ENFit syringes. Working with a cross functional multi-organizational team of pharmacy experts, suppliers, manufacturers, and regulatory stakeholders understanding how to access ENFit Syringes easily outside of hospitals will allow the continuity of care to take place outside of the hospital while using the new enteral feeding system. Working with the correct individuals will allow us to better understand how ENFit syringes will be reimbursed.

Tool Task Force

Background: Comprehensive tool kits are needed to educate the caregiver and patient on the working ENFit components throughout a patient's stay at a hospital. It is necessary that the moment a patient receives an enteral feeding component with an ENFit connector or transitions to a product with an ENFit connector to understand how the connectors work and the necessary components they will be needed to continue the appropriate care at home.

Objective: To formalize all the necessary components of existing tools kits to create one master tool kit. One master tool kit can be used to train the clinical staff on the new ENFit connectors but also educate the patient.

FMEA Task Force - Lead by Deborah Pasko, ASHP

Background: Implementing an entirely new enteral feeding system is a big transition for a facility and requires careful planning. Even the most carefully thought out plans may not be implemented perfectly. Understanding the possible failures will help facilities. Failure Mode and Effects Analysis (FMEA) is a proactive tool, technique and quality method that enables the identification and prevention of process or product errors before they occur.

Objective: To understand any potential failures and conduct a system reliability study. Doing so will allow facilities to understand and develop action plans for any failure. This team will be

led by ASHP and ISMP will understand any potential failures and conduct a system reliability study for all to adopt and utilize within their own facility.

Cleaning Protocol

Background: Another key component that was discussed during the Summit was a cleaning and infection prevention protocol of the ENFit connector. Clinicians and supporting organizations have taken the lead on this and will be formalizing a test plan to determine the best methods for cleaning and infection recommendations. This group will also be engaging the FDA, manufacturers, and stakeholders for input to ensure a robust study is completed so a cleaning procedure can be published. ASPEN, Children's Mercy Hospital, GEDSA and others will be meeting at Clinical Nutrition Week to determine the materials needed and testing procedures. If you plan on attending CNW and would like to be part of this task force please reach out to us for additional information.

Objective: Determine clinically based best practices and protocols for cleaning ENFit connectors and keeping tubes patent over time. Included will be a microbial study to determine the best methods for cleaning to eliminate the build-up of bad bacteria harmful to the tube fed patient.