ENFit Advocacy Meeting

July 26th, 2017
10:00am EST
## ENFit Advocacy Meeting

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
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<td>Supply Readiness</td>
<td>Cara Larimer, Brad Gray, Lisa Fohey, Devon McMichael</td>
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<td>Distributor &amp; Supplier Challenges</td>
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<td>Patient Journey</td>
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<td>1:45-2:00</td>
<td>ENFit Transition Success Story</td>
<td>Valley Children’s Hospital</td>
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<td>Breakout Sessions – Breaking through the Stagnation</td>
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<td>Break for Refreshments</td>
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<td>3:00-3:30</td>
<td>Recap from Breakout Sessions</td>
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<td>3:30-4:00</td>
<td>Next Steps and Closing Remarks</td>
<td>ENFit Today</td>
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Anti-Trust Statement

- GEDSA is a 501(c)(6) US Federal tax exempt Non-Profit Trade Association incorporated in the State of Ohio, USA.
- GEDSA’s mission is to promote initiatives surrounding safe and optimal delivery and connectivity.
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- Any questions regarding the meaning or applicability of this policy, as well as any concerns regarding activities or discussions at GEDSA functions, should be promptly brought to the attention of GEDSA’s executive director, officers, and/or legal counsel.
## Attendees

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<th>AAMI</th>
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Objective of Meeting

• Recalibrate on why we are here.
• Consider ways to drive adoption
• Arrive at an action plan to potentially include:
  • Discontinuation of legacy devices?
  • Removal or discontinuation of transition connectors and other adapters?
  • Regulations or enforcement tactics?
  • Other?
Reducing the Risk of Medical Device Tubing Misconnections

Tom Hancock - GEDSA
Tubing Misconnections Adverse Events

- **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 death

- **Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff**, delivering air to the bloodstream, causing death

- **Feeding tube was coupled with a peripheral line of a pregnant woman**, resulting in enteral nutrition delivered directly into the bloodstream; neither the 35-week-old fetus nor the woman survived
A Global Effort to Enhance Patient Safety

Technical Experts

ISO 80369
Small-bore connectors

Clinical Experts

Regulatory/Standards Experts
ISO Design Standards Developed for System-Specific Applications

Requirements:

- Not connectable with others in series
- Rigid or semi-rigid
- Passes Misconnection, Risk Analysis, Usability/Human Factors Testing
- Not connectable with Luer or needleless connector ports

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<th>Neuraxial</th>
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GEDSA’s MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity.
## Supporting Organizations

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<th>AHRMM</th>
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<td>Advancing Safety in Medical Technology</td>
<td>Advancing Health Resource &amp; Materials Management</td>
<td>American Society for Healthcare Risk Management</td>
<td>Safe and Trusted Healthcare</td>
<td>For Healthcare and Healthcare Professionals</td>
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<td>Vizient - Comprehensive Healthcare Intelligence</td>
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<td>Healthcare Trust</td>
<td>Improving Patient Safety in the Hospital Environment</td>
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Tubing Misconnections Impact

Peggi Guenter
Cost of Enteral Misconnections

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

Discuss the healthcare dollars cost of misconnections. The human cost is beyond dollars.
Background

First case report of an inadvertent connection of an enteral infusion into the IV system reported in 1972 in *The Lancet*. Wallace et al reported that a “milk drip” of pasteurized cow’s milk intended as therapy for a patient with exacerbation of a duodenal ulcer was accidently connected to an IV line.

ECRI Top 10 Technology Hazards

ECRI published “Top 10 Technology Hazards for 2012”, a practical guide to identifying technology risks at health care facilities. The guide addresses ten medical technologies that most frequently lead to patient injuries (and in our experience, malpractice lawsuits):

- Alarm hazards
- Exposure hazards from radiation therapy and CT
- Medication administration errors using infusion pumps
- Cross-contamination from flexible endoscopes
- Inattention to change management for medical device connectivity
- **Enteral feeding misconnections**
- Surgical fires
- Needlesticks and other sharps injuries
- Anesthesia hazards due to incomplete pre-use inspection
- Poor usability of home-use medical devices

Published Cases in the Literature

116 published cases as of 2010. Like most errors, highly under-reported.
Simmons, et al. Reports

Case Reports
(N = 116 in 34 reports)
Patients
• Adult (N = 60)
• Child/infant
  (N = 30)
• Not specified
  (N = 26)
Simmons, et al. Reports

116 Cases

21 Died (18%)
95 Survived (82%)
84 of the 95 had at least 1 diagnosis reported
37/84 respiratory conditions including arrest (44%)
16/84 had sepsis (19%)
11/84 had neurological harm (13%)
8/84 had renal impairment (9.5%)
1/84 had hypersensitivity/hypercoagulopathy
Cost of Death in Hospital

Costs to be discussed entail only healthcare costs, do not include human suffering or lost productivity.

Death in Hospital: The cost of their hospital stays was about $20 billion. The Federal agency'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, versus an average of $9,447 for patients who were discharged alive. (AHRQ)

Does not include cost of malpractice lawsuits which adds another layer of cost to the institution and/or clinicians.
Cost of Respiratory Insufficiency

• AHRQ database
• 0.91% had a diagnosis code for Respiratory Insufficiency, Arrest and Failure (RIAF) that was not present on admission.
• Mortality rates were higher for RIAF cases (34.6%) than non-RIAF cases (1.2%, p<0.001).
• Lengths of hospital and ICU stays were higher for RIAF cases (11.5, 5.8 days) than non-RIAF cases (4.1, 2.9 days), respectively.
• Total hospital costs were higher for RIAF cases ($24,578) than non-RIAF cases ($6,370).
• About 40% of the costs of RIAF cases were attributed to ICU stay.
Cost of Sepsis

• Mean expense per hospital stay was over $18,000 in 2013.
• Hospitalizations from sepsis 70% more expensive than the average stay.
• Sepsis resulted in nearly 1.3 million discharges that year from U.S. hospitals, an increase of 19% from 2011.
• Sepsis was also the most expensive hospital condition billed to Medicare, accounting for 8.2% of all Medicare costs incurred in 2013.

Celeste M. Torio, Ph.D., M.P.H., and Brian J. Moore, Ph.D. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013 HCUP statistical brief #204
Cost of Neurological Disease

• Strokes: Lifetime costs per patient are estimated at between $59,800 and $230,000. (WHO: Neurological disorders)

• Traumatic brain injury: cost of TBI in 2010, including direct and indirect medical costs, is estimated to be approximately $76.5 billion. Additionally, the cost of fatal TBIs and TBIs requiring hospitalization, many of which are severe, account for approximately 90% of the total TBI medical costs. (CDC

https://www.cdc.gov/traumaticbraininjury/severe.html)
Oral Medications Inadvertently Given via the Intravenous Route

- 20 reports 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 drug was administered using a parenteral syringe in many of these cases.
- ISMP now asking for updated data from PA Patient Safety as well as ECRI and California PSO

Tubing Misconnections Impact

Glenda Rodgers
## ENFit Advocacy Meeting

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Worldwide Adoption of ENFit

Tom Hancock
ENFit Global Adoption Status

Global Adoption is Well Underway with Europe Leading*

**Europe**
- > 50% depending on market
- UK, Netherlands, France, Italy, Belgium >90% transitioned

**North America**
- < 30%
- Primary concern over adequate supply
- Law (AB444) in CA effective July 1, 2016

**South America**
- < 5%
- Transition anticipated to commence in 2018

**Asia**
- <5% adoption
- Transition anticipated to commence in ‘18
- 2019 for China & Japan

**ANZ**
- > 50% adoption

**Eastern Europe, Middle East & Africa**
- < 30%

* Adoption rates are only rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world.
ENFit Survey Results

Has your facility transitioned to ENFit?

- Yes: 72%
- No: 28%

Obstacles from Transitioning:

- No Safety Benefit: 10%
- Product Not Available: 60%
- Inadequate Education: 20%
- Lack of Mandate: 15%
- Implementation Uncertainty: 15%
ENFit Survey Results

If so, check the following obstacles your hospital may have faced:
UK Adoption
Cornelia Haindl
ENFit Introduction in the UK

Connie Haindl & Mark Fisher PhD, BSc

Head of Product Development & Technical Manager

GBUK Healthcare
GBUK Transition to ENFit®

- GBUK supplies medical devices to England, Ireland, Scotland, Wales & Europe.
- Support adoption through GEDSA & Enteral Plastics Safety Group (EPSG) from existing reversed Luer to ENFit feeding system in the UK.
- Authorities from the National Health Services (NHS), the Dept. of Health and Key Opinion Leaders recognized importance and encouraged adoption.
Collaboration through EPSG

- Collective effort (including (NHS) through EPSG in promoting awareness of ENFit and adoption in a timely fashion.

- Benefits of ENFit were recognized and compliant with a global standard, rather than a national standard in enteral care.

- Worked closely with other industry partners to ensure stock was available and various components of ENFit across the portfolio of products.
ENFit Transition Plan

- Established countrywide “Go-Live” date
- Outlined timeline of when/how long transition connectors and legacy feeding tubes would be available
- Worked closely with a number of key trusts (health systems) to kickstart the adoption process & demonstrate how system worked.
- Compromised on market demand for a lot of different transition adaptors due to lack of confidence in supply
ENFit Transition Adapters Became Crutch

- Key concern for patients with long term tubes in place.
- Caregivers didn’t want to remove legacy feeding tubes and place ENFit feeding tubes prematurely.
- Led to an extended period of transition with transition connectors.
- Transition connectors promoted by Dept. of Health/NHS, contributed to delay in adoption & promoted status quo
- Hospitals used supply of legacy products, rather than swapping/destroying and taking on new ENFit product.
Challenges with Implementation

• Disjointed roll-out
• Gap between transition sets and ENFit feeding tube & syringe availability
  • Not all feeding tubes were available at the same time
• Information on transition was too far in advance
• Challenges with ordering (right codes, product descriptions and pictures)
• Would have liked more frequent and timely communications
Current ENFit Status in the UK

• Currently UK has greater than 90% adoption rate of ENFit.

• Critical Success Factors
  • Support of NHS administration and healthcare systems helped encourage quick conversions
  • Focus on education and why change from safe national solution (Reverse Luer) to safer global solution (ENFit)
  • Industry worked together in sharing knowledge, experience & supply
  • EPSG were key in promoting awareness across the healthcare sector
  • Encouraged the demise of transition connectors and the full adoption
Patient Perspective
Brandis Goodman
Brandis Goodman, Director of Parent Education
Experience tube feeding since January 2010
Member of A.S.P.E.N.
Founded in 2010
Pediatric Focus
Broad reach
  - 50K followers on Facebook, 24% outside the U.S.
  - More than 55K visits to the FTAF website each month
  - Education materials widely distributed
Working with GEDSA since 2014
Why We Support the ENFit Transition

• Patient Safety. Not only for misconnections, but for disconnections.
  • Many misconnections do not get formally reported
  • Disconnections are frequent problem
• Parents (and tube feeders) go through great lengths to maintain enteral connections.
• Transition adaptors create more challenges in feeding and medication administration.
• Pediatrics are already using small bores – nearly all have 18Fr or smaller feeding tubes and are successfully feeding a variety of enteral diets.
Feeding Tube Awareness ENFit Survey

We conducted a survey of 534 Parents/Caregivers and Tube Feeders on our Facebook page. Survey was shared beyond our page.

- 85% Parents/Caregivers
- 11% Adult Tube Feeders

- 56% tube feeding for 3 years or longer
- 17% tube feeding a year or less

- 76% United States
- 24% Outside the United States – primarily Canada, United Kingdom, Australia

- Conducted June 2 – 5, 2017
Most are Familiar with ENFit

- Educating about ENFit has been challenging with the delays in the transition. More than three-quarters are at least somewhat familiar with ENFit.

Q: How familiar are you with ENFit? (n=534)
Most Already Exposed to ENFit

- The majority are already using transition adapters or ENFit to ENFit connections.

Q: Have you started using any ENFit tube feeding supplies?  (n=534)
Transition Adapters are Problematic

- Nearly half are having problems with transition adapters at least once a week. This is consistent with what we hear and experience as users.

Q: If you are using ENFit transition adapters, how often have you had problems with them? (n=291)

- Never: 14%
- Hardly ever: 26%
- Every few weeks: 11%
- Once a week: 7%
- Few times a week: 22%
- Every day: 19%
ENFit to ENFit is More Favorable

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

Q: If you are using ENFit to ENFit connections, what has your experience been? (n=106)

- Very Positive: 44%
- Somewhat Positive: 25%
- Somewhat Negative: 14%
- Very Negative: 13%
- N/A: 4%
Comments About Their Responses

Positive comments reflect a more secure connection.

“Connection feels secure, never had one break or leak, and my toddler can’t unscrew it.”

“It’s so much easier to use ENFit to ENFit rather than using the fiddly adapters which were often taken off and lost.”

“At first I hated the new connection, but then I adjusted and learned to use the little connector for medications. Eventually I actually loved that the connection would not come apart on its own and we no longer had to worry about the med port accidentally opening and making a mess. My son has continuous feeds.”

Negative comments show the need for greater education about supply use and cleaning.

“Easy too overtighten and crack the screw fitting. Also very hard to clean the screw fitting. But connects well and no leakage.”

“We often have problems unscrewing the ends. Other than that issue we find they work well.”

“I find the connectors dribble fluid during changeovers and the new twisty things hard to keep clean.”

Q: Please explain your answer to question 4. (n=89)
Some of the less positive experience is that they do not consistently get all ENFit supplies.

“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 cant 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.”

Q: Please explain your answer to question 4. (n=89)
Syringe Gap

In another survey, we found that many people aren’t getting the syringes they need for feeding or medication delivery from their medical supply companies.

Survey conducted June 21 – July 6, 2017 (n=354). Mostly from the US (93%) and most haven’t converted to ENFit syringes (7% know they are using ENFit syringes).

Does your medical supply company currently provide you with all the syringes you need each month for...?

Feeding
- Yes: 51%
- No: 29%
- Not Using: 20%

Medication
- Yes: 37%
- No: 56%
- Not Using: 9%
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<td>10:15-10:45</td>
<td>Tubing Misconnections Impact &amp; Background</td>
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<td>Peggi Guenter &amp; Glenda Rodgers</td>
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<td>Peggi Guenter</td>
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<td>Dose Accuracy</td>
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<td>Laura Zoerner</td>
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<td>Rx to OTC Designation</td>
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Cleaning the End of the Feeding Tube or Extension Set

• Peggi Guenter, PhD, RN, FAAN, FASPEN
• Senior Director of Clinical Practice, Quality, and Advocacy
• American Society for Parenteral and Enteral Nutrition
Cleaning the Tube End

- Proximal end of feeding tube now a male end and will need periodic cleaning to remove medication and formula debris
- Suggest a brush like a toothbrush or bottle brush and warm water daily and prn for tubes, particularly those in the home
- Products on the market to perform cleaning (brush devices)
- Need evidence-based protocols so cleaning studies are needed
How to Clean ENFit Nasogastric, Tryanspynoric, Oral and PEG tubes

ENFit items

Supplies needed for cleaning
1. Clean cup with tap water
2. Enteral syringe
3. Good quality toothbrush used only for cleaning the feeding tube

Step 1
Wash your Hands

Uncap the ENFit connections, wet the toothbrush and clean the cap by rotating and brushing. Make sure bristles go into the cap.

Step 2

Fill the enteral syringe with clean water and rinse the cap.

Step 3

****Repeat Steps 2 and 3 if not clean****
Step 4
Fill the enteral syringe with clean water. Plug the center hole of the feeding tube with bristles of the toothbrush. Forcefully flush the moat with 2-3 mls of water, use more water and repeat if necessary.

Step 5
Clean the moat by rewetting the toothbrush, rotate and brush the grooves and the bottom of the moat. Make sure bristles go into the center hole.

Step 6
Rewet the toothbrush and plug the center hole of the feeding tube with the bristles of the toothbrush. Fill the enteral syringe with clean water and forcefully flush the moat with 2-3 mls of water.

*** Repeat steps 4-6 if not clean***

Step 7
Remove any water in the cap or moat by drying with a clean cloth or paper towel.

Step 8
Clean the syringe with clean water and let dry.

Step 9
Clean the toothbrush with clean water and let dry.
How to Clean ENFit Extension Tube

Supplies needed for cleaning
1. Clean cup or bowl with tap water
2. ENFit Enteral syringe
3. Medium bristle toothbrush for cleaning extension tubing

Step 1
Wash your hands

Step 2
- Disconnect extension tube from child
- Soak extension set in clean water for 1 minute

Step 3
- Clean the cap and moat if it looks dirty.
- Wet the toothbrush
- Brush the cap and moat for 15 seconds
- Make sure the bristles get into the grooves and bottom of the moat
**Repeat steps 2 and 3 until clean**

Step 4
- Rinse with clean water
Step 5
- Remove any water in the cap or moat
- Dry with a clean cloth or paper towel

Step 6
- Clean the syringe with clean water
- Let dry

Step 7
- Clean the toothbrush with clean water
- Let dry
- Change the toothbrush monthly – toothbrush is only good for one month
Cleaning Research Protocol

• Developed by Beth Lyman RN, MSN, CNSC and others
• Protocol submitted to Biosafety Committee and IRB at Children’s Mercy Hospital in KC, MO
• The specific aim of this study is to evaluate the efficacy of a cleaning protocol for ENFit connectors by:
  1. Visible evaluation of the cleaning procedure prior to and after cleaning using a nominal scale to score the effectiveness of the cleaning procedure.
  2. Evaluation of the cleaning procedure after application of an environmental cleaning gel using a black light and nominal scale to score the effectiveness of the cleaning.
Cleaning Research Protocol, continued

• Staff nurses will clean the connectors using either a toothbrush or a commercial brush
• They will clean connectors contaminated with chocolate formula, medications, or a cleaning product that detects proper cleaning.
• Cleaning will then be rated by independent observers who are blinded to which cleaning method was used.
• Research will be conducted in September 2017 and data analyzed in October, manuscript written in November-December.
Dose Accuracy

Laura Zoerner
ENFit and Dose Accuracy Background

- “Reducing the risk of (tubing) misconnection requires a complete design change with correlating standards established and adopted worldwide across the industry” (GEDSA website)
  - This is achieved through ISO 80369-3 for enteral connections

- Dose delivery accuracy (which includes the entire system) ensures that the correct dose is prepared and administered to the patient

- There is no standard to reference for dose delivery accuracy applicable to enteral syringes and/or administration systems

- Non-enteral reference points, such as hypodermic syringe performance standards (ISO 7886), provide information on container measurement accuracy, but not delivery accuracy

- ISO 7886-1 is a standard for hypodermic syringes, which covers requirements and test methods for various syringe parameters including tolerance on graduated capacity. Enteral device manufacturers use this standard only as a proxy for enteral/oral syringes to test tolerance on graduated capacity as there are no current standards in place for enteral/oral syringes on dose accuracy.
Dose Accuracy Concerns Raised

• Clinicians:
  • Raised concerns on the dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation
  • Indicated a dosing accuracy expectation of ± 10% for a target volume of 0.2mL when delivered from a 1mL syringe

• Industry:
  • There is no global standardized test (ISO, AAMI, ASTM, EN, etc.) for manufacturers to use to evaluate dosing accuracy for syringes
  • In absence of a standardized test, no baseline data existed for comparison
Performance Testing

- GEDSA members assessed the ability of the standard ENFit® syringe to meet a +/-10% delivery accuracy and determined that syringe sizes of 5 mL or smaller may require a “low dose tip” ENFit® connector design to meet this target.

- Performance testing was then conducted by a third-party, accredited test lab. The following enteral syringe types were evaluated to determine the performance of the low dose design and to establish a baseline for the performance of existing syringes:
  - Leading brands of existing enteral/oral syringes (*all male tip*)
  - Female Luer lock (*reverse system used in the UK*)
  - Proprietary reverse system syringes currently marketed
  - Standard ENFit® syringe tip
  - Proposed ENFit® low dose tip syringe

OBJECTIVE: Address delivery accuracy concerns raised by clinicians and determine the baseline performance of existing enteral syringes/systems

Results were submitted to the FDA to support 510(k) submissions for the low dose tip design.
Information that has been circulated by BD stating the acceptable performance variance for dosing accuracy is +/- 5% is incorrect. Dose accuracy requirements are not defined in ISO 7886-1.

-Per ISO 7886-1, tolerance on graduated capacity requirements vary based on a formula that uses the syringe size and prescribed dose.
Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes *(Delivering 0.2 mL in a 1 mL syringe)*

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.
Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes  *(Delivering 0.2 mL in a 1 mL syringe)*

- **ENFit® Low Dose Tip**
- **Existing enteral/oral**
- **Reverse Proprietary**
- **Reverse Female LL**
- **Standard ENFit®**

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.
ENFit® Dose Accuracy Solution

- The ENFit® Low Dose Tip (LDT) syringe was designed to specifically address the dose accuracy concerns
  - Design is proposed for inclusion into ISO 20695 standard and is under review by the committee

- LDT adds an internal male lumen to the standard ENFit® female syringe
  - This mimics the functionality of traditional male oral/enteral syringe designs
Misconnection Risk Assessment

- The ENFit® Low Dose Tip provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections.
- The addition of the internal male feature to the standard female ENFit® connector was evaluated for tubing misconnections across the other small bore connector designs of the ISO 80369 series.
- The conclusion of this analysis was that the ENFit® LDT provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections.
Usability Testing Top Level Summary

- 148 respondents worldwide representing pharmacy, nursing and caregivers evaluated the ENFit® LDT using current practices and methods for filling and administering enteral doses
- The respondents were able to complete the filling or administering of water or thick liquids (Pepto Bismol®/Children’s Tylenol®/Paracare®) with the LDT successfully
- Responses about the LDT performance were consistent across all user groups, regardless of the tasks evaluated

Overall, users found the ENFit® LDT design feature acceptable for filling and administering enteral doses
Recommended Syringe Use

- **Method of filling the syringe** (*cup fill vs straw/adapter fill*)
  - Using a straw or adapter to fill the syringe will deliver higher accuracy for each dose, similar to how other reverse orientation syringes are filled currently
  - The straw or adapter reduces the potential for excess residual fluid to be outside the fluid pathway

- **Removal of Residual Fluid**
  - The LDT internal feature behaves similarly to the male tip of existing oral/enteral syringes
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to move fluid that may be outside the fluid pathway
Low Dose ENFit® Syringe Conclusion

**Performance Test Results** *(when used as instructed)*:
- Substantially equivalent to standard orientation (male) enteral/oral syringes
- Performs better than Reverse Orientation (female tip) syringes
- Use of an adaptor (such as a straw) provides better performance than a cup fill

**Misconnection Risk Assessment:**
ENFit®, including the Low Dose Tip, mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit

**Usability:**
No significant difference between use of ENFit® LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)
Rx to OTC Designation
Background

• Janelle Flaherty RD CNSC
• Enteral Operations Dietitian Manager
• Coram CVS Specialty Infusion Services
• GEDSA Advisor and Task Force Lead
Medication Administration at Home

**Legacy Feeding Systems:**
- Use Enteral/Oral (E/O) tip syringes for medication
- E/O syringes available without prescription at retail pharmacy and on-line

**ENFit Feeding System**
- Requires ENFit Tip Syringes
- All ENFit devices including syringes are considered Rx only
- Retail pharmacists may not be aware of the need for ENFit Tip Syringes
- Awareness and availability currently rate limiting factors on ENFit Adoption
Solving the ENFit Tip Syringe Access Issues

**Rx to Overt the Counter (OTC)**
- Requires FDA clearance for each company's set of devices
- Establish Instructions for Use (IFU) for average user
- Usability studies demonstrating IFU can be followed without supervision of a physician

**Timing (Anticipate 6-12 Months)**
- Usability Testing
- FDA Review and Manufacturer 510k pre-market clearance (TBD)
- Manufacturing and product availability (check with supplier rep)
What to Do Until Then?

**Retail Pharmacy**
- Communicate to pharmacist patient has ENFit Feeding Tube
- Requires ENFit Tip Syringe for medication administration
- Check with distributors for product availability

**Home Infusion Providers**
- Providers may offer limited supply at no cost
- Additional supply may be available as cash pay option

**On-line Options?**
- Some online options may supply with proof of prescription
Training
Stephanne Hale
Master Tool Kit

- ENFit Background
- Medication Preparation & Administration Guide
- Patient Discharge Instructions & Talk Sheet
- Interactive Demonstration Model
- ENFit product bins
- StayConnected Wristlets & Brochures
- Transition Team Manual
ENFit Transition Planning Recommendations

Establish Cross Functional Team
• Determine transition plan and timing (“Go Live Date”)
• Maintain ongoing communication with ALL team members
• Develop tools to assist with engaging/educating team members, internal/external care givers, patients, families and others
• Partner with your suppliers and distributors

Work with Supplier Representatives:
• Understand ENFit product availability and timing
• Obtain Crosswalks (legacy to ENFit item numbers)
• Consider all components and accessories of feeding system

Secure Syringe & Pharmacy Supply:
• Key components to ENFit Transition
• Smaller sizes should have Low Dose Tip
• Verify adequate supply to meet your needs
• Consider a second and possibly third supplier

Visit Stayconnected.org
• Tools, Newsletters, FAQs and much more
ENFit Advocacy Meeting

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>12:45-1:45</td>
<td>Supply Readiness</td>
<td>Cara Larimer, Brad Gray, Lisa Fohey, Devon McMichael</td>
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<td>Distributor &amp; Supplier Challenges</td>
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<td>1:45-2:00</td>
<td>ENFit Transition Success Story</td>
<td>Valley Children’s Hospital</td>
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<td>Breakout Sessions – Breaking through the Stagnation</td>
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<td>Break for Refreshments</td>
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<td>3:00-3:30</td>
<td>Recap from Breakout Sessions</td>
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<td>Next Steps and Closing Remarks</td>
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GDSA
Supplier & Distributor Challenges
Manufacturer’s Role

Laura Zoerner – GEDSA Executive Board, Treasurer
What is the Role of the Manufacturer?

**BENEFITS**

- Manufacturer’s provide a benefit to the Customer
  - Represent Voice of Customer (Needs of Patient, HCP’s, distribution network, Key Opinion Leaders)
  - Develop new products to improve patient care and improve user satisfaction
  - Comply with state, federal, and global regulations

**METRICS**

- Various metrics are used to measure performance of Manufacturers
  - Market projections (growth, size of market, ability to penetrate)
  - Market share
  - Customer satisfaction (both in product performance and in inventory levels)
  - Wall Street expectations
What Causes Difficulty for Manufacturers?

Pain Points:

• Return on Investment (ROI) for ENFit project is significantly delayed – the delayed market conversion in the US due to low dose tip and now the slow adoption is negatively impacting ROI

• Slow inventory movement – currently stocking old and new inventory both, reducing efficiency and burdening funding (tying up funds)

• Slowing any consideration for future ENFit work (e.g. new product development, etc.)
Manufacturer

ROLE:
• Innovate & Supply

MOTIVATION:
• Market Share & Profitable Growth

PAIN POINT:
• Manufacturing/forecasting 2 sets of supply (Legacy & ENFit)
Distributor

ROLE:
• Aggregate & Distribute

MOTIVATION:
• Improve Margins & Reduce Days on Hand

PAIN POINT:
• Supply without demand (Carrying legacy & ENFit systems)
Group Purchasing Organization

ROLE:
• Vet Vendors & Establish Price

MOTIVATION:
• Contractual Compliance

PAIN POINT:
• Lack of ability to enforce
Hospital

ROLE:
• Source Materials & Provide Acute Care

MOTIVATION:
• Triple Aim (Quality, Cost & Outcomes)

PAIN POINT:
• No driving force (cost savings or mandate)
• Perceived Lack of supply (Legacy or ENFit)
• Fear & hard work to change
Home Care

ROLE:
• Source Materials & Provide Post Acute Care

MOTIVATION:
• Quality, cost of care, and positive patient outcomes

PAIN POINT:
• Must follow lead of Referral Source (Hospital)
• Forced to carry legacy and ENFit
Patient/Caregiver

ROLE:
• Receive Safe Care

MOTIVATION:
• Outcomes & Quality of Life

PAIN POINT:
• Disruption of therapy (1 system at Home, different system elsewhere)
Supporting Articles & Recommendations

1. **The Joint Commission** issues “Sentinel Event Alert, Issue 36: Tubing misconnections- a persistent and potentially deadly occurrence to increase awareness of tubing misconnection errors”

2. **Association for the Advancement of Medical Instrumentation (AAMI)** publishes “ISO 80369-1 Small bore connectors for liquids and gases applications” and is recognized by the FDA

3. **The Food and Drug Administration (FDA)** publishes a guidance on “Safety Considerations to Mitigate the Risks of Misconnections with Small bore Connectors Intended for Enteral Applications”

4. **Institute for Safe Medication Practices (ISMP)** publishes Medication Safety Alert” ENFit Enteral Devices are on their way... Important safety considerations for hospitals”

5. **Center for Medicare & Medicaid Service (CMS)** addresses State Survey Agency Directors on “Luer Misconnection Adverse Events”

6. **ECRI Institute** releases “Critical Notice–Avoid Fatal Misconnections with ENFit-compliant Feeding Tube Connectors”

7. **American Society for Parenteral and Enteral Nutrition (ASPEN)** publishes “A.S.P.E.N. Supports Major Medical Device Changes for Improved Patient Safety”

8. **American Journal of Health-System Pharmacy (ASHP)** publishes “Transition to ENFit enteral devices: Special challenges for pediatric institutions”

9. **British Association for Parenteral and Enteral Nutrition (BAPEN)** published “ISO 80369-3: IMPORTANT UPDATE – ENFit Implementation”

10. **National Health Services (NHS)** publishes a patient safety alert “Stage One: Warning Managing risks during the transition period to new ISO connectors for medical devices “

For full references and articles visit StayConnected.org
# Stakeholder Supply Stagnation

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<th>Distributor</th>
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Influenced By

- HOSPITAL FDA
- HOSPITAL
- TJC CMS
- HOSPITAL
- HOSPITAL & HC
Recommendation:

**FDA**
- Establish deadline for removal of legacy tubes and transition connectors
- Guidance/Recommendation to Health systems

**TJC**
- Formally include in survey/audit
- Train Surveyors
- Re-issue SE 53 with stronger language encouraging adoption.

**CMS**
- No longer reimburse legacy tubes or transition connectors
- Reimburse for all ENFit devices including medication syringes

**Manufacturers**
- Align to effective date to stop making legacy devices.

**Hospitals**
- VA establishes Patient Safety Mandate
- Follow Surveyors & Reimbursement

**Distributors**
- Align to effective date to stop selling legacy devices.

**Home Care**
- Will follow hospital & reimbursement

**Patient/Caregiver**
- No disruption of therapy
- Reduced Readmissions
Wish List

• FDA
  • Establish deadline for removal of legacy tubes and transition connectors
  • Guidance/Recommendation to Healthsystems

• The Joint Commission
  • Formally include in survey/audit
  • Re-issue SE 53 with stronger language encouraging adoption.

• CMS
  • No longer reimburse legacy tubes or transition connectors
  • Reimburse for all ENFit devices including medication syringes

• Veterans Affairs
  • Patient safety mandate to implement ENFit®.

• Distributors: Align to effective date 6 months as to when they stop selling devices.