Launch Team Tool Kit
Approach

Aware
- Communicate to all Stakeholders
  - Assemble X-Functional Team
  - Determine Impacted Depts.
  - Alert Post-Acute Continuum

Prepare
- Build Supply & Educate Users
  - Identify all Suppliers & Build Crosswalks
  - Establish & Communicate Demand
  - Educate all Impacted Staff

Adopt
- Carefully Transition & Discharge
  - Establish “Go Live” Date
  - Build product inventory
  - Ensure Support at Discharge

Measure
- Monitor Supply & Capture Lessons Learned
  - Measure team’s ability to adopt change
  - Optimize Inventory Management
  - Provide feedback on areas for improvement
Objective:
Communicate to all Stakeholders and anyone who manages enterally fed patients or supplies

Tasks:
- Assemble cross-functional team of both internal and external partners, suppliers and vendors
- Determine all impacted departments
- Alert transfer hospitals and other post-acute continuum of care
ENFit Communication Summary

What: New ISO 80369 design standards established for small bore connectors, starting with enteral feeding

Why: Help prevent tubing misconnections and wrong route delivery of fluids, nutrition formula, and medication

Who: GEDSA Manufacturer Members lead ENFit introduction/adoptions, backed by the FDA, Joint Commission and Clinical Associations

Where: Global initiative with adoption in process around the world. Law in California (AB444) and mandated in UK/NHS

When: Throughout 2017 and 2018

How: Implemented across all hospital systems and healthcare settings impacting any department or function that place or manage enterally fed patients

For More Information about ENFit visit www.stayconnected.org
Who will be Impacted?

- Knowledge of ENFit
- Medication delivery and feedings
- Ability to educate patient/caregiver of changes

- General awareness
- Ordering medications with correct route of delivery
- Care coordination

- Workflows
- Medication Preparation
- Coordination of homecare
- Delays in discharge

- Cost
- Storage space
- Availability of supplies
- Forecasting
Key Decisions

- Syringe Vendor
- Use of ENFit syringes for oral medications
- Nursing workflow
- Removing legacy tubes from stock
- Which patients would receive ENFit tubes
- Patient education & discharge supplies
- EMR Build
Build Interdisciplinary Task Force Team

Team Responsibilities:
- Identify Impact of ENFit Change
- Hospital Areas
  - Products
  - Policies & Processes
  - External Partners
- Develop Meeting Planning Guide
- Lead ENFit Implementation
Identify Hospital Areas Impacted

Consider:
- Departments, functions and all those that care for tube fed patients
- Practices & Procedures impacted in departments
- Products that may need to change
- Product used & surgically placed for tube feeding
Identify Products Impacted

A. Administration Sets
B. Syringes
C. Feeding Tubes
D. Pharmacy & Other Ancillary Devices
Administration Sets for Enteral Feeding

**Transition Sets:**

- Most suppliers of administration sets have already converted to ENFit and included a transition connector (Adapter)
- Transition Connectors will no longer be needed with ENFit feeding tubes

**Types of Administration Sets**

- Spike & Bag Pump Sets
- Gravity Feeding Sets
- Other Bolus Feeding Devices
Syringes Used for Enteral Feeding

Types of syringes commonly used for feeding, flushing and administering medication

• Enteral/Oral Syringes (E/O syringes)
• Luer Slip Tip Syringes
• Catheter Tip Syringes
• Common size syringes (.5, 1, 3, 5, 6, 10, 20, 35, 60 mL)
• Safety Syringes

ENFit Feeding Tubes will require **ENFit Tip Syringes**
Feeding Tubes Impacted

Types of tubes commonly used for feeding

• Gastrostomy (G-Tube)
• Low Profile Feeding tubes and corresponding extension sets
• Nasoatraumatic (NG-Tube)
• Nasojugal (NJ-Tube)
• Gastrojejunal (GJ-Tube)
• PEG Tube Y-Ports
Pharmacy & Other Ancillary Items Impacted

- Bottle fills caps
- Medication bottle adapters
- Fill Straws
- Syringe caps
- Tamper evident solutions
- Prefilled syringes
- Light protective solutions
Off Label Use – NO ENFit Connectors

• Any devices not indicated for enteral feeding will not have an ENFit connector

• Examples of off label feeding tubes
  • Foley Catheters
  • Red Rubber Catheters
  • Other Urinary Catheter

• Check with your supplier representative regarding tubes specifically designed for drainage like salem sumps about

• Luer syringes will remain on the market but will not be compatible with any ENFit feeding device
Objective:
Build Supply and Educate Users

Tasks:
• Identify all Suppliers & Build Crosswalks
• Establish & Communicate Demand
• Educate all Impacted Staff
Identify Policies & Processes to be Changed

Consider:

• Understand, access and adapt existing processes and protocols to carefully understand changes when new ISO 80369 connectors are introduced.

• For each application there will be a transition period. During that transition period to understand potential risk and use of adapters (FMEA).

• Standardize an error prevention technique during transition to ensure all clinical staff understand how to use all products.
Example – Nursing Patient Care Policy & Procedure

• Some processes or policies may not need to change but may need updating with correct names
• Understand changes to discharge planning, ordering medication to pharmacy, and patient education

<table>
<thead>
<tr>
<th>UWHealth</th>
<th>Effective Date: February 2, 2015</th>
<th>Administrative Manual</th>
<th>Nursing Manual (Red)</th>
<th>Other</th>
<th>Policy #: 2.22 AP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Original □</td>
<td>Revision ☒</td>
<td>Page 1 of 3</td>
<td>Title: Unclogging Enteral Feeding Tubes (Adult &amp; Pediatric)</td>
<td></td>
</tr>
</tbody>
</table>
Identify External Partners to Coordinate Implementation

**Best Practices:**
- Include external partners in meetings
- Discuss changing demand for ENFit products with suppliers
- Set expectations on management of
- Communicate your ENFit “go-live” date
Forecast New Item Needs

1. Survey tubes and syringes in use today for enteral feeding
   • Check all departments that manage patients (OR, ER, IR, ICU, NICU, Pharmacy, Skilled Nursing Facilities, step down or post-acute, Home Infusion).
   • May be managed through central supply.
2. Determine which supplier/manufacturers are used today for each tube used for feeding.
3. Run a report to identify monthly and annual volumes for usage of each company’s legacy device and size of device listed above.
   • Consider eliminating product used less often
   • Annual usage by department throughout the hospital
4. Determine steady state demand for feeding tubes
   • Most on-label feeding tubes a 1 for 1 ratio for future usage plus any census growth
   • Off label feeding tube use (ex. Red Rubber or Foley Catheters) will require consultation with those physicians and department that placing these tubes
     • Communicate necessity to switch to ENFit devices
     • Determine % of use for enteral feeding.
Forecasting Syringe Usage

• Consult with pharmacy, nursing staff, risk managers and other administrative staff used to determine syringe types used today

• Decision Points:
  • Will your hospital use ENFit Tip Syringes only for enteral administration or will ENFit tip syringes be used for oral administration of medication as well
  • Type and size ENFit Tip syringes to replace legacy syringe use.

• Determine % of use of enteral/oral syringes, Luer syringes, or catheter tip syringes used enterally to identify ratio for forecasting based of past volumes
  • If ENFit Tip syringes will be used enterally and orally, then apply a one for one ratio
  • Luer Slip Tip and Catheter Tip Syringes may still be required for other applications, however, there may be a percentage of use enterally that should be discussed

• Check with your syringe supplier representatives for their indications for use and they may also have tools to assist in forecasting
Secure New Item Crosswalk from Each Supplier

• Make sure each item used in the past has a corresponding new item number for the ENFit compatible item for each supplier
• Determine if there are any gaps between legacy devices and new ENFit devices
• Discuss gaps with each supplier to identify suitable substitutes
• Identify back-up suppliers, particularly for syringes. Multiple suppliers may be required to ensure adequate supply at least in the short term
• Your group purchasing organization may have a list of suitable substitute products for any gaps unfulfilled by current suppliers
Build New Item Crosswalk

Crosswalk Benefits:

- Identifies Products Impacted & Corresponding Item # changes
- Match existing products to Suppliers’ NEW ENFit products
- Understand manufacturers availability & timing on each item
- Identify critical path products to begin transition to ENFit

| Legacy Products | Corresponding ENFit Products |
Review Forecast Including Safety Stock & Pipeline

• Discuss preliminary forecast with supplier rep to determine:
  • Product availability for each types and size of tubes, syringes, and ancillary items.
  • Identify when each supplier will have the most common items available for use.
  • Determine the incremental amount of safety stock and/or “pipeline inventory”
    required to ensure product is available at the right place and the right time in case of
    spikes in usage.

• Adjust forecast for “go-live” date to include safety stock and pipeline
  inventory necessary:
  • Often times safety stock would be considered 2-3 times steady state demand.
  • Pipeline is that product that is in addition to what is in use, that sit on shelves at
    distributor, hospital warehouse, etc.
Discuss “Go-live” Date with Cross-Functional Team

• Training time with physician, pharmacy, and nursing
• Preparation with case managers and discharge planners
  • Educating patients at discharge about new feeding and supplies needed
  • Alerting home infusion or home medical equipment companies that they will need adequate supply to manage patient at discharge
• Natural tendency for cross-functional team will be to delay this challenging transition until they “have to” or are “told to”
• Issues related to supply concerns may be reason for delay
Consider the Risk of Not Adopting

• Tubing misconnections while somewhat rare, do happen,

• Events are underreported and when they do happen, they can be fatal

• A safer system does exist and has been available for some time, yet your hospital has not adopted while others have

• If an event occurs, it will likely be the hospital’s responsibility for any damages
Provide Education & Training on ENFit Products
ENFit® Interactive Teaching Station

Description:
Hands on tool that allows clinicians, hospital staff, and patients/caregivers to touch new connectors.

Tool Kit Includes:
• ENFit Background
• Medication Preparation & Administration Guide
• Patient Discharge Instructions & Talk Sheet
• Interactive Demonstration Model
• StayConnected Wristlets & Brochures
• Transition Team Manual
• Assembly Instructions

*Products are not included with the tool kits, it is recommended to reach out to your enteral device supplier for samples to fill the tool kit*
ENFit Training Materials on StayConnected.org

Description
On the StayConnected.org website there are videos for everyone to view that cover all things ENFit.

Educational Videos:
- Misconnection Risk Patient Stories
- Standards Process & ENFit Background
- ENFit Success Stories
- Medication Preparation and Administration
Other Training Tools

Tools:

- Just-in-time teaching sheets
- Medication administration infographic
- Checklists
- FAQ Documents
- References
Objective:
Carefully Transition all products and patients to ENFit and ensure a safe transition at discharge

Tasks:
• Establish “Go Live” Date
• Build product inventory
• Ensure Support at Discharge
Finalize and Share Forecasts

• Finalize forecast of each item outlined in crosswalk
• Layer in additional needs for safety stock and pipeline inventory
• Review forecast with distributors and/or each supplier to determine:
  • What products are available and in inventory
  • What products must be secured from supplier/manufacturer
  • Timing for all products to be in inventory and ready to be shipped to hospitals
  • Any gaps in supply from any company or any item
• Confirm delivery dates of critical path items to support Go-Live Date
Set Go-Live Date

- Develop recommendation for “Go-live” date from supply side
- Discuss jointly with suppliers and distributors to determine logistics and timing for securing product in inventory to transition
- If managing on behalf of a hospital system consider a “roll out”:
  - Transition one hospital at a time sequentially over a short period of time
  - Reduce overall inventory burden and allow hospital system to learn as you go
- Other Considerations:
  - Transition adult populations ahead of pediatric if awaiting specialty items such as ENFit Low Dose Tip syringes, prefilled syringes and syringe pump calibration
  - Short term use of transition connectors as product is flowing through from legacy feeding tube to new ENFit feeding tubes.
  - While the system is intended to abolish the need for adapters, short term use many be necessary for a smooth transition
Establish Inventory Management Plan

• Identify flow through method of inventory management from legacy to ENFit compatible tubes, syringes, and supplies.
• Determine incremental stocking item needs and related spacial requirements
• Set discontinuation dates for legacy items such that legacy tubes and syringes will not be accepted into inventory unless emergency situation
• Monitor inventory of impacted legacy and ENFit devices ahead of Go Live date and throughout transition to avoid any overstocking
• Clarify any returns policies with distributors and or suppliers
Launch Day

- Create an atmosphere of excitement
  - Wristlets
  - Balloons
  - Buttons

Staff-Up Training Team
Managing Patients at Discharge

**Best Practices:**

- Send patients home armed with proper instructions and supply requirements
  - Feeding Tube Specifications
  - Feeding Method
  - Syringe Requirements
  - Other Device Needs
- Share Key Contacts Information for:
  - Case Managers
  - Home Health Nursing
  - Retail Pharmacy
  - Home Medical Equipment/Home Infusion

<table>
<thead>
<tr>
<th>Tube Feeding at Home Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is recommended to have a healthcare provider fill this portion out.</td>
</tr>
</tbody>
</table>

**Supply Information:**

<table>
<thead>
<tr>
<th>Formula:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Order detail:</td>
<td></td>
</tr>
</tbody>
</table>

**Feeding Tube:**

<table>
<thead>
<tr>
<th>Type:</th>
<th>Manufacturer:</th>
<th>Size (French):</th>
</tr>
</thead>
</table>

- for Low profile Feeding Tube: French: Length: __________
- Extension set (circle): Continuous Bolus Length: 12" 24"

**Method:**

- Bolus Gravity Pump
  - pump: Name: Manufacturer:____________

**Syringes needed:**

**Key Contacts:**

<table>
<thead>
<tr>
<th>Phone</th>
<th>email</th>
</tr>
</thead>
</table>
Discuss ENFit Change with Patients/Caregivers

Key Points:
- Global change that hospitals around the world are adopting
- Your hospital wants to be at the forefront of this important safety initiative
- Addresses risk of tubing misconnections that can happen in hospitals and at home
- Standardization ensures that all enteral devices fit together and things that shouldn’t, won’t

Best Practice:
- Show patient how administration sets, tubes and syringes all easily fit together with ENFit

Going Home with an ENFit® Feeding Tube

New connectors for feeding tubes are now available. ENFit was designed specifically to standardize the connection between tube feeding devices and ensure they will not fit into other types of devices (such as IV ports), to reduce the possibility of harmful misconnections.

Administration Set
Administration sets have the new ENFit® female connector and the limited use Transition Connector to facilitate compatibility with existing (legacy) ports.

Administration Set
Syringes used to administer medicine, flush, hydrate or bolus feed through feeding tubes will now require ENFit® connectors.

Feeding Tube
To ensure small volume dose accuracy, small syringe sizes may require an ENFit® Low Dose Tip.

Administration/pump sets will have a new ENFit female connector. Feeding tube ports will have male ENFit connectors. A quarter turn will lock the connector in place.

Access tube feeding resources and support through The Oley Foundation www.oley.org, (518) 262-5079 or Feeding Tube Awareness Foundation www.feedingtubearawerness.org

Get more information on the new ENFit connector transition at www.StayConnected.org.
Ask Patients/Caregivers to “Pass it On”

### Key Points:
- Since ENFit is a new global standard, not everyone in the healthcare community is aware.
- Enlist their help in communicating the change.
- Let them know, they need to advocate for appropriate supplies.
- Share the talking points for each type of healthcare provider.

### Best Practice:
- Contact local retail pharmacy, Home Health Nurse or HME the patient will most likely use.
- Stress the importance they understand the change and offer/use the right supplies.

---

**Talking to your retail pharmacist, home health caretaker or home medical equipment supplier:**
- Understand this is a new global initiative, yet some remain unaware.
- Do not be surprised if they are learning this for the first time from you.
- Ask them to learn more at [www.stayconnected.org](http://www.stayconnected.org)

**Retail Pharmacy:**
**Recommendation:**
- Speak with your pharmacist when you first call or hand in your prescription and tell them that medication must be delivered through an enteral feeding tube with an ENFit connector.
- Questions to ask your retail pharmacist:
  - Can they get access to ENFit syringes to deliver medication through the feeding tube?
  - Will the pharmacist ensure there is ample supply in stock for future prescriptions and refills?

**Home Health Caretaker:**
**Recommendations:**
- Bring any ENFit education material or resources home with you for your caretaker to review.
- Questions for your home health caretaker:
  - Are they familiar with the new ENFit connectors for tube feeding?
  - Are they able to confidently administer the care needed with the new ENFit system?
  - Do they have resources or contact information for questions specific to the new ENFit connectors?

**Home Medical Equipment Supplier:**
**Recommendation:**
- Speak with your home medical equipment supplier 4-5 days before you will need any ENFit products.
- Questions for your Home Medical Equipment Supplier:
  - Do you have adequate supply of ENFit products for my monthly use?
  - Are there any anticipated lead times or delivery delays of ENFit products?
Objective:
Monitor Supply & Capture Lessons Learned

Tasks:
• Measure team’s ability to adopt change
• Optimize Inventory Management
• Pass Along Your Success & Lessons Learned
Measure Team’s Ability to Adopt Change

• Continue holding internal team meetings to monitor the transition
  • Evaluate product performance and share feedback with suppliers
  • Reach out to all departments to ensure understanding of remaining challenges
  • Continuously monitor progress, follow-up and review

• Consider completing facility or system wide survey for continuous improvement

• Provide Feedback to Suppliers and Vendors on their Performance
  • Follow up with distributors and suppliers to assure no supply concerns
  • Follow patients after discharge to ensure access of ENFit Suppliers with home products.
  • Gain their feedback on lessons learned from their perspective to help with future implementations
Optimize Inventory Management Plan

• Conduct regular feedback sessions with supplier and distributors representatives
• Monitor supply performance and quickly communicate any gaps or unforeseen challenges with supply
• Consider areas for consolidation of inventory
  • Syringe types and sizes
    • If hospital decided to keep oral tip syringes, re-evaluate decision to see how hospital is functioning with multiple types of syringes
    • Review most commonly used sizes of syringes
  • Tube types and sizes
    • Confirm reduction in off label use of tubes and communicate any increase in demand for ENFit feeding tubes
Pass Along Your Success & Lessons Learned

- Document lessons learned for hospitals next transition to ISO 80369 standard connectors (likely NRFit)
- Interview key stakeholders, team leaders and cross-functional team members on known and unforeseen obstacles and how they were best resolved
- Align to what the biggest keys to success for the team
- Consider recording teams answers through interviews and sharing at [www.stayconnected.org](http://www.stayconnected.org).

For more information on sharing success stories, please contact [info@gedsa.org](mailto:info@gedsa.org) for assistance.
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 (ASJPEN) 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”


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