

Reducing the Risk of Medical Device Tubing Misconnections

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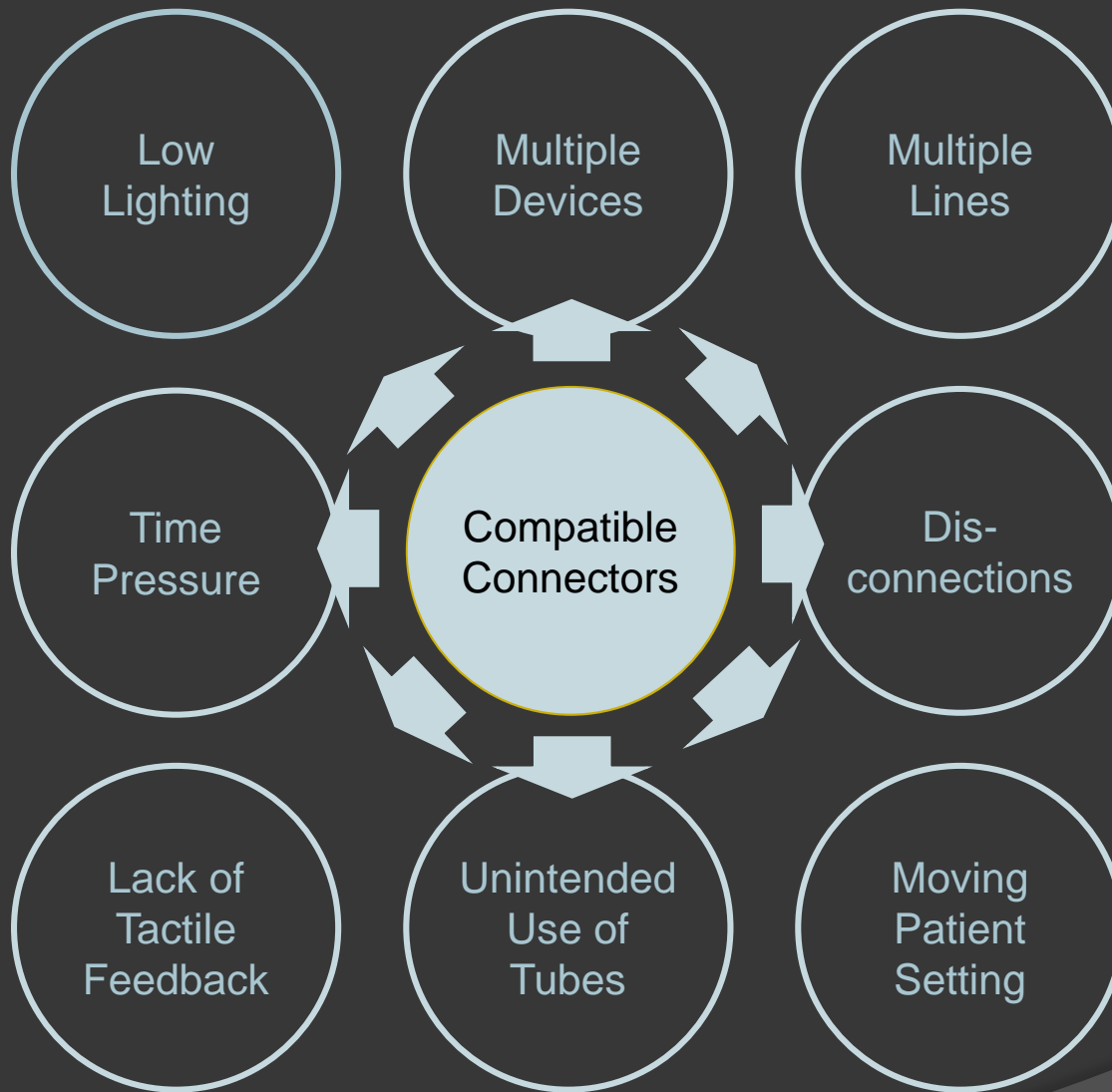
Peggi Guenter, Ph.D., RN, FAAN, FASPEN
Senior Director
ASPEN

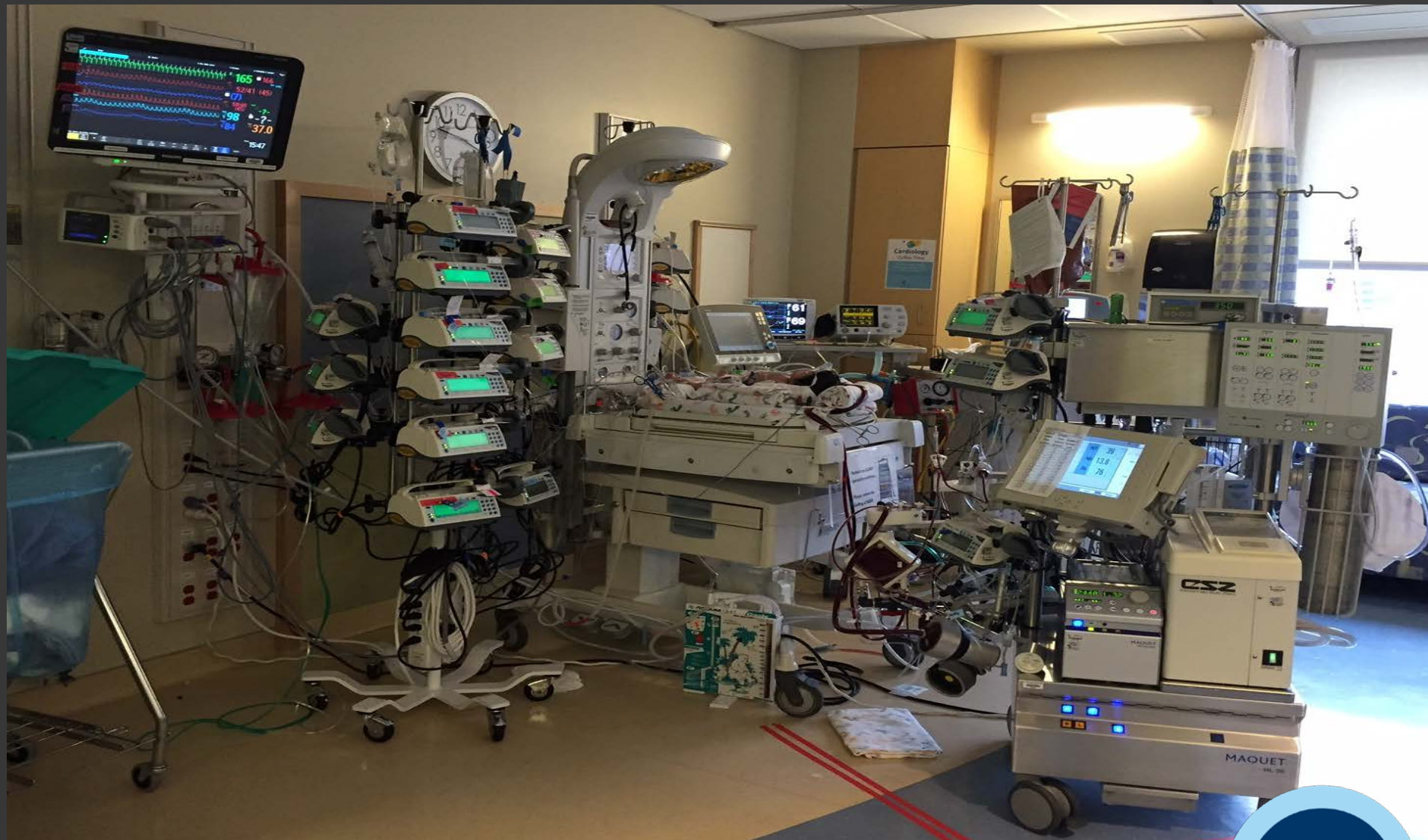


Tubing Misconnections Adverse Events

- **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



ISO Design Standards Developed for System-specific Applications

80369 Series

-1 General requirements

Respiratory	Enteral	Urological	Limb Cuff	Neuraxial	Intravascular
-2	-3	-4	-5	-6	-7

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

ISO Design Standards Developed for System-specific Applications

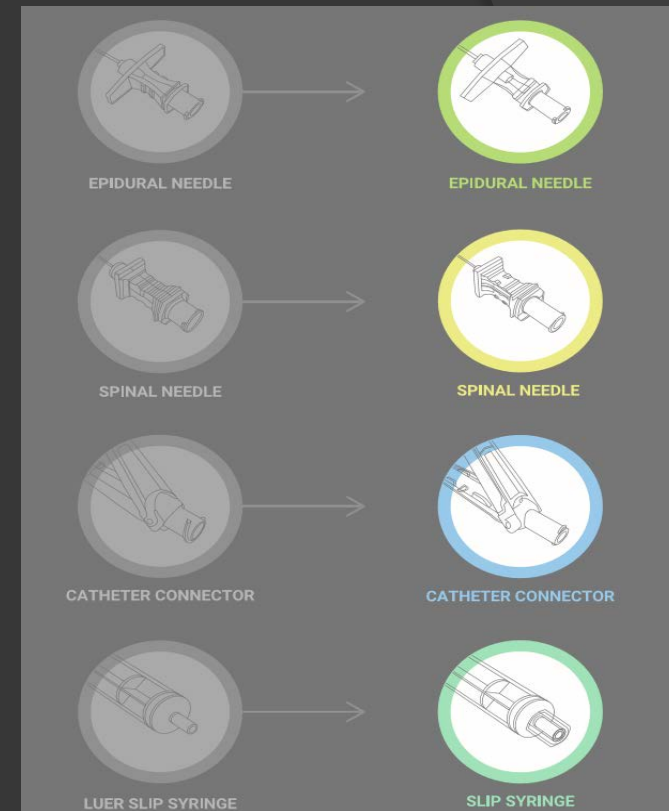
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Examples of Devices impacted by ISO 80369-6 (NRFit):

- Spinal needles
- Epidural needles
- Catheter connectors
- Loss of resistance syringes
- Epidural / spinal syringes
- Epidural pump tubing / extension tubing
- Filters, Filter Straws, Filter Needles
- Stopcocks used with Manometers



Tom Hancock, MBA
Executive Director
GEDSA



MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity



GEDSA Members

Abbott

A. Hopf

Alcor Scientific

Amsino

Bard

Baxter

B Braun

Boston Scientific

Cair Lgl

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Codan

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Degania

Enteral UK

Fresenius Kabi

Halyard

Intervene

Medela

Medicina

Medline

Medtronic

Moog

NeoMed

Nestle

Nutricia

Qosina

Smith's Medical

UComfor

Vesco Medical

Vygon

VR Medical/Kentec

Xeridiam

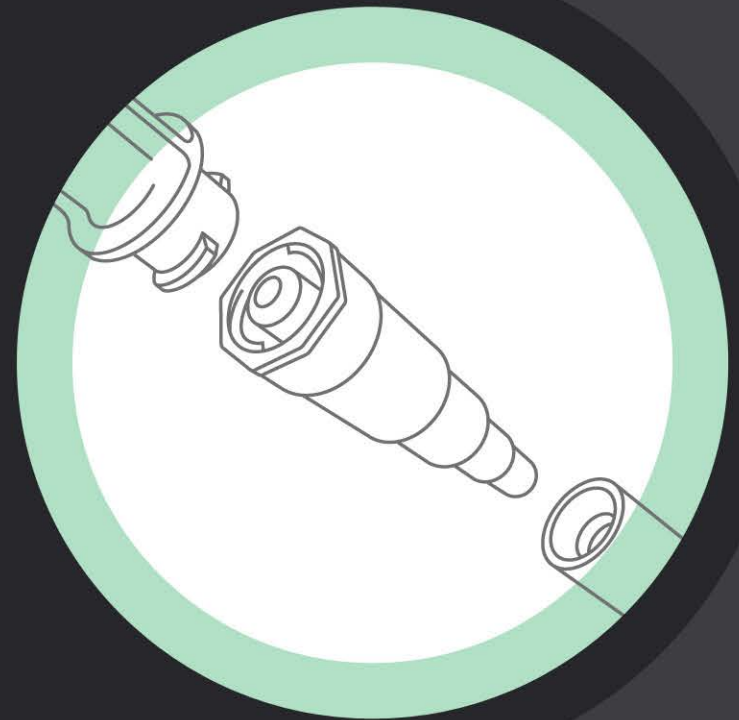
Supporting Organizations



TRANSITION SET

ENFit Transition Connector

- Temporary fitment
- From new ENFit connector to current feeding port



GOAL: Eliminate the Long-term Need for Adapters

ADMINISTRATION SET

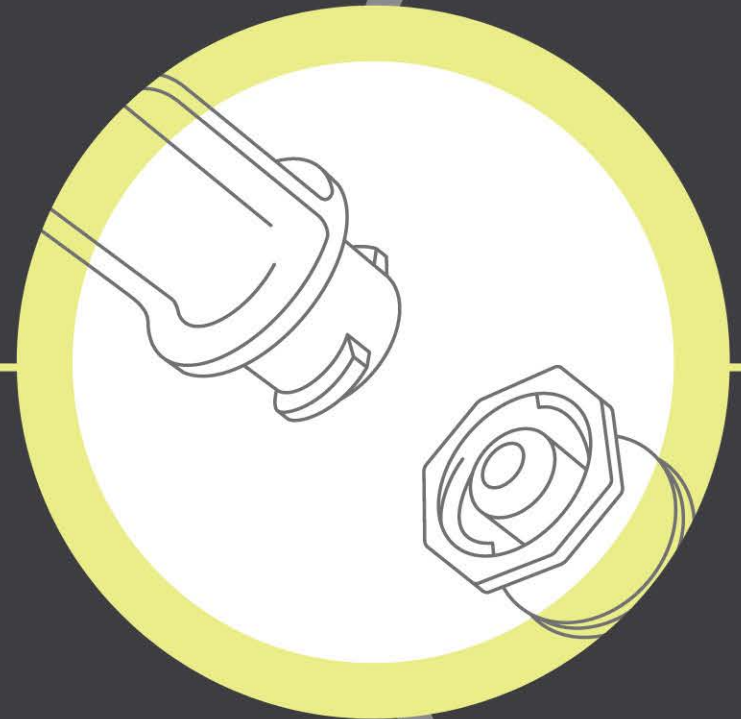
From Male Stepped Connector
to Female ENFit:

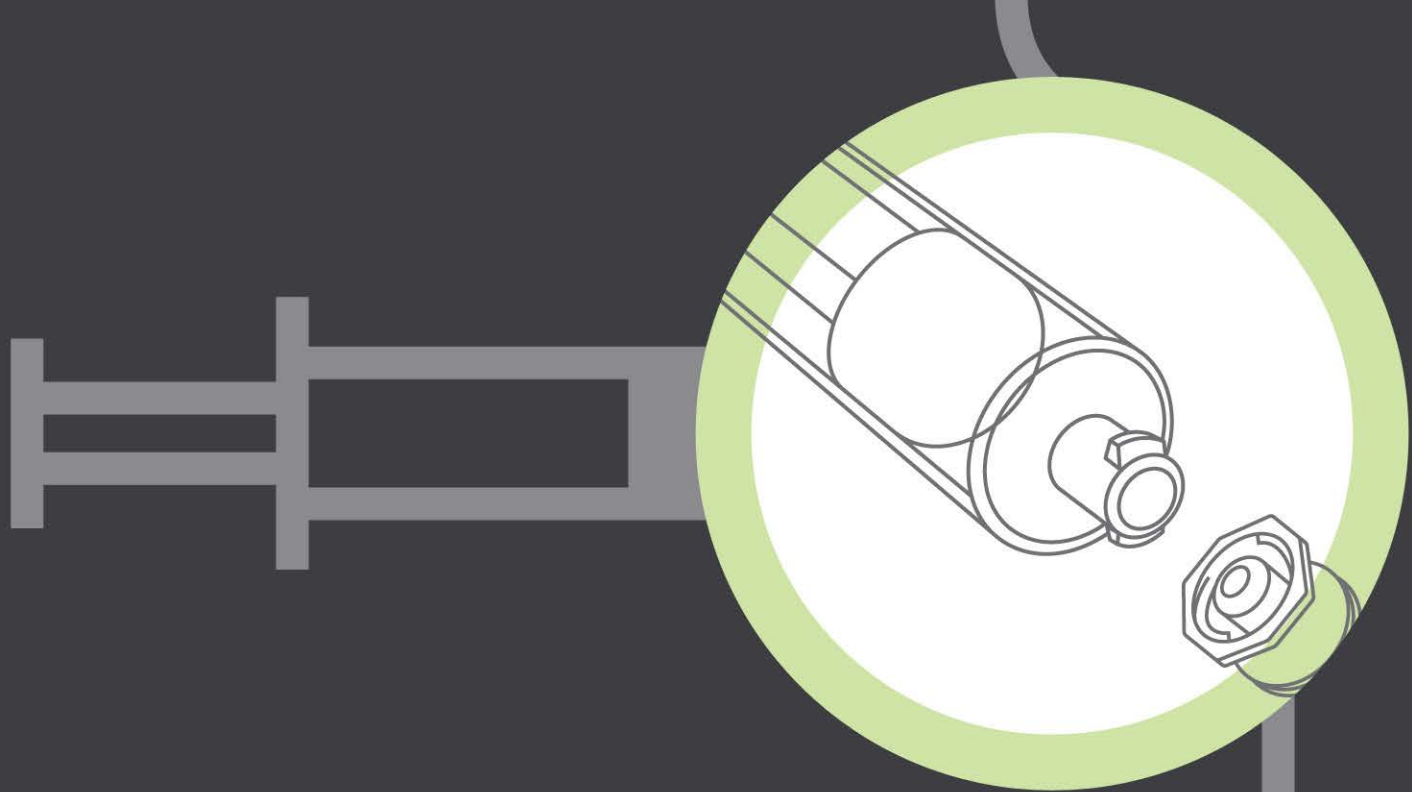
- Pump Set
- Gravity Set
- Other Bolus Feed or Venting Devices

FEEDING TUBE

From Female Flexible Port
to Male ENFit:

- NG Tubes
- G Tubes
- Low-Profile Extension Sets
- J-Tubes





SYRINGES

From oral, catheter, or Luer tip to enteral-specific fitment:

- Administer Medicine
- Flush
- Hydrate
- Bolus Feed



Marcus Dortch, PharmD
Senior Director
HealthTrust Clinical Pharmacy Services



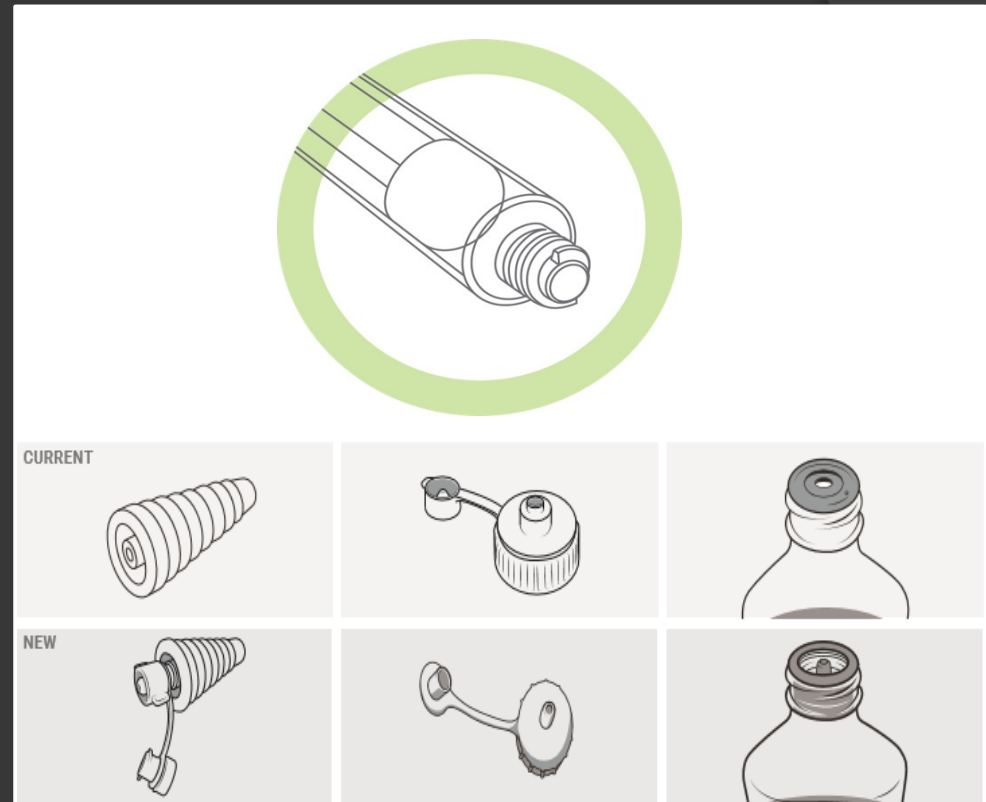
Pharmacy Recommendations

Filling & Administering Medication



Understanding Changes in Pharmacy Practice

- Everyday Pharmacy items will change to be compatible with new ENFit Syringes
- Process remains the same for filling and administering
- ENFit syringes require a twisting motion to connect and disconnect from ancillary items

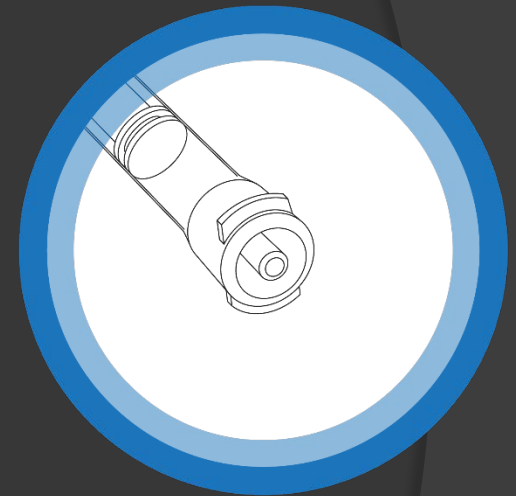


Dose Accuracy Concerns

- Clinicians:
 - Clinicians have raised concerns on dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation
 - Clinicians and pharmacists indicated dosing accuracy expectation of $\pm 10\%$ a target volume of 0.2 mL (*when delivered using a 1 mL syringe*)
- Industry:
 - There is no current standard (ISO, AAMI, ASTM, EN) dosing accuracy requirement or specification for oral/enteral syringes
 - Dosing accuracy is not a standard test performed by syringe manufacturers, therefore no baseline data exists for comparison

Proposed ENFit[®] Low Dose Tip Syringe

- Designed to specifically address dose accuracy concerns.
- Standard ENFit female syringe tip with an internal tip lumen.
- Orientation/configuration is similar to Luer lock syringes.



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



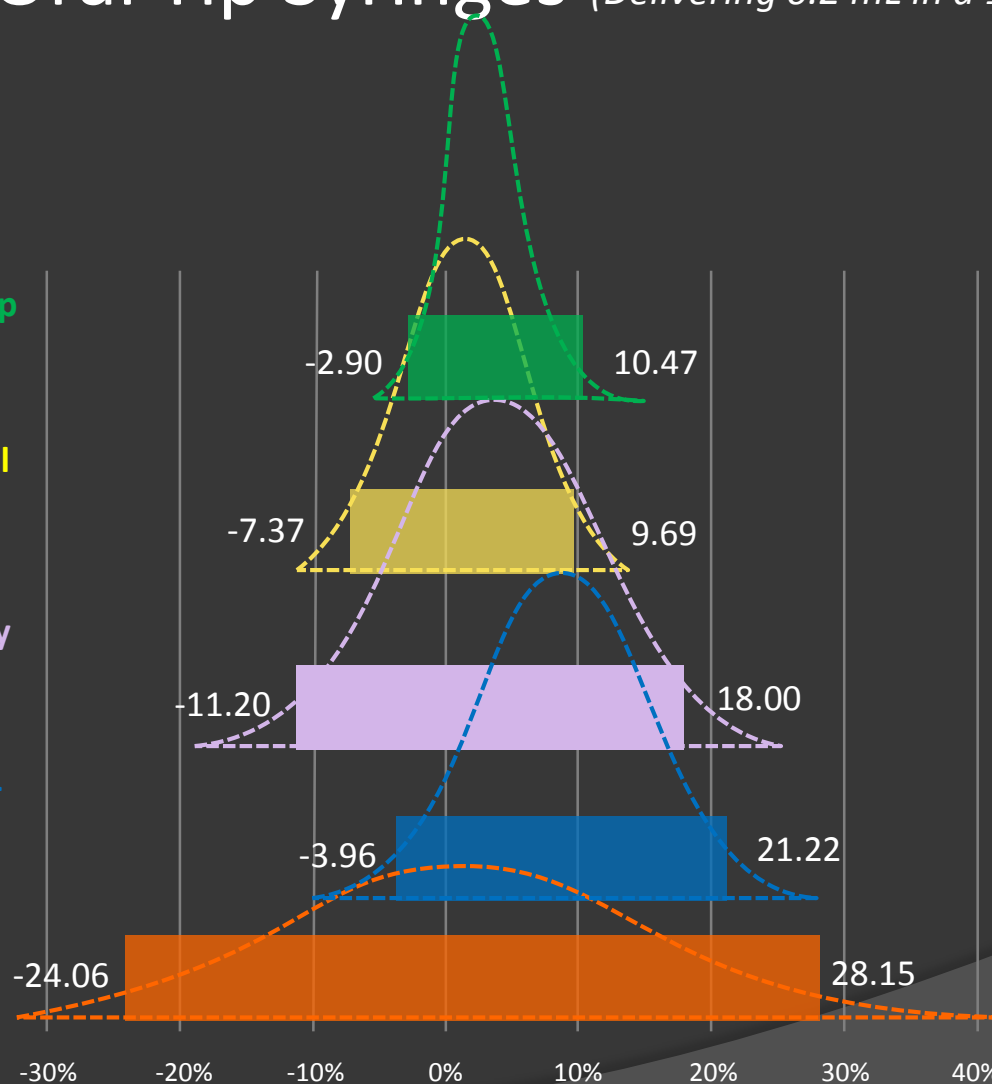
Reverse Proprietary



Reverse Female LL



Standard ENFit®

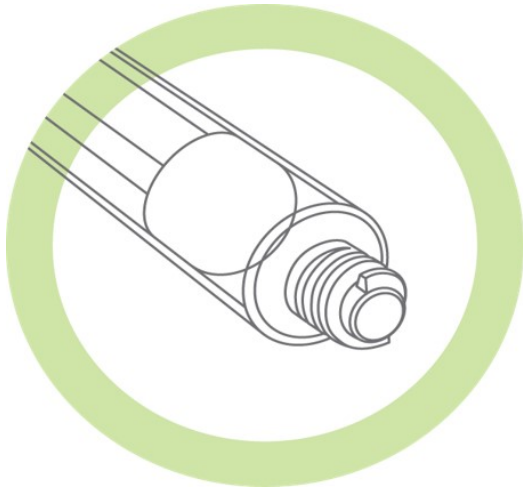


Solid block = 95% confidence interval of the data set.
Curve – fitted distribution to the generated data.

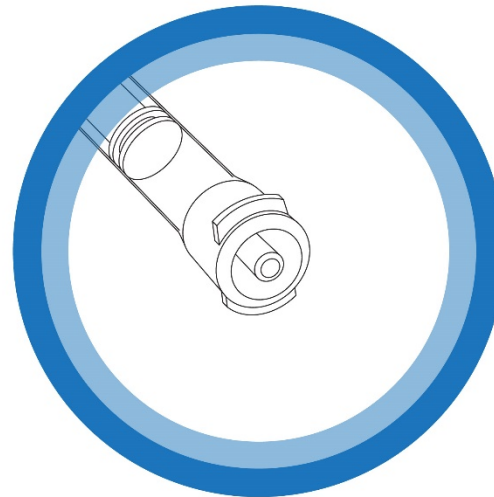
Note: Target is $\pm 10\%$ of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set..

Standard Tip vs. Low Dose Tip

ENFit Standard Tip Syringe



ENFit Low Dose Tip Syringe



Filling from Cup

Ensure fluid is removed from
mote by tapping or filling



ENFit Low Dose Tip Syringe Conclusion

Performance Test Results (when used as instructed):

- Dose Accuracy range of -2.90% to +10.47% (95% CI)
- 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:

Mitigates risk of tubing misconnections and provides a clinical benefit that outweighs the risk of its use

Usability:

No significant difference vs. current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)

FDA Clearance:

Thoroughly reviewed and cleared at least four 510(k) submissions for ENFit Low Dose Tip Syringes

Planning for the Transition

Pharmacy Considerations

- ⦿ ENFit syringes:
 - Both enteral and oral use
 - Enteral applications only (E/O syringes for oral applications)
- ⦿ Forecast facilities syringe usage. Plan on 2-3 months for initial shipments to ensure adequate supply
- ⦿ Determine timing for items like tamper evident caps, prefilled syringes and filling devices
- ⦿ Prior to the go-live, understand which floors need prefilled syringes and ensure adequate supply (ex. Children's Tylenol in PICU)

Resources on StayConnected.org

Pharmacy Resources:

- Preparing & Administering Medication In-patient and out-patient infographics
- Medication Administration educational videos
- Just-In-Time Teaching Tool to review new ENFit system with staff
- ENFit Low Dose Tip research paper

Procedure for Inpatient Settings: Preparing and Administering Medications Using ENFit®

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MEDICATION PREPARATION: FILLING A SYRINGE USING A BOTTLE FILL CAP

Step 1. Make sure that the medication bottle has an ENFit compatible fill cap.



FILLING THE SYRINGE WITH A MEDICATION STRAW

When an ENFit bottle cap will not fit the medication bottle or it is impossible to remove the current bottle adapter, fill the syringe using a medication straw.



FILLING THE SYRINGE USING A MEDICATION CUP

NOTE: Filling the syringe via a dose cap is not the preferred method for filling the syringe.



NOTE: Critical medications such as narcotics or cardiac medications that have a narrow therapeutic index MUST be free of medication to the rear of the low dose tip syringe.



Preparing and Administering Medication using ENFit
Procedure for Use in the Inpatient Setting

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Betty Brant, RN, BSN, MHA, CNOR, CSPDT
Implementation Manager and
Clinical Resource Manager
Mercy Hospital

Process & Timeline

Aware

Communicate to
internal and external
stakeholders

Assemble Cross Functional Team
Determine Impacted Departments
Identify all Suppliers
Alert Post-Acute Continuum

Prepare

Build Supply
Educate Users

Build Crosswalks
Establish & Communicate Demand
Educate all Impacted Staff

Adopt

Carefully
Transition &
Discharge

Establish "Go Live" Date
Build product inventory
Ensure Proper Support at Discharge

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Assemble Cross-Functional Team



Topics for Team Meetings

Awareness

- Internal All Functions & Departments Impacted
- External/Care Continuum awareness (owned and partner organizations)

Workflow Changes

- Patient/caregiver changes at discharge
- Medication route delivery for pharmacy orders
- ENFit Tip Syringes instead or in addition to E/O Syringes

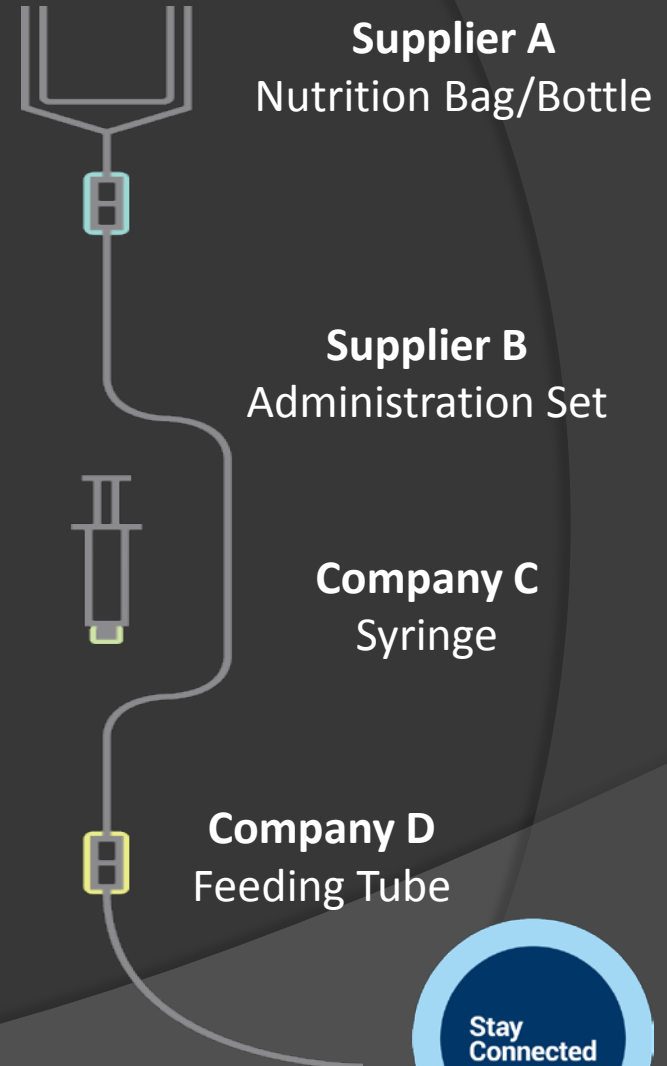
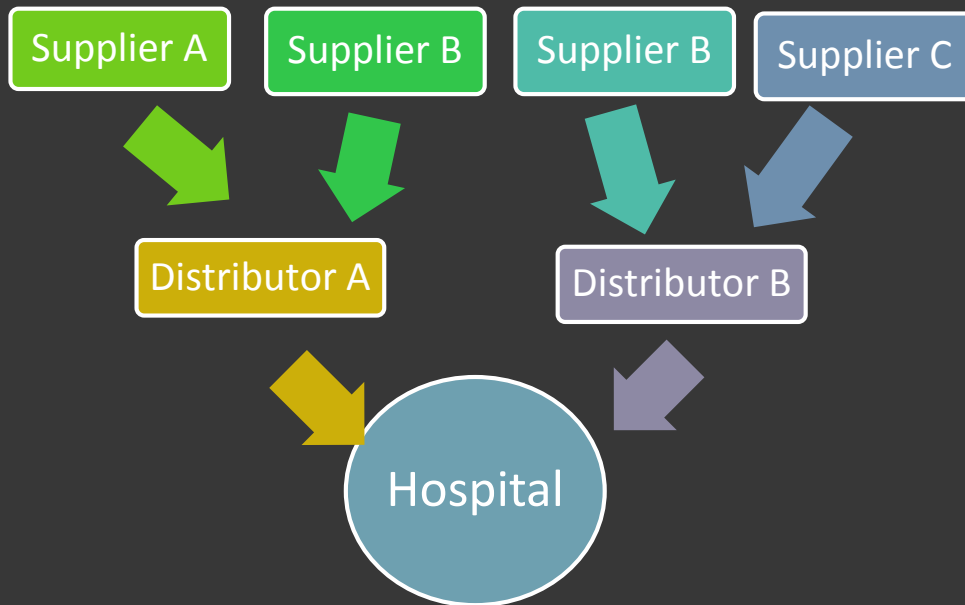
Care Coordination

- Discharge planner education
- Supply available for patient needs at home for feeds and medications
- Coordination of home care needs and supplies & school needs

Supplier/Distributor Partnership

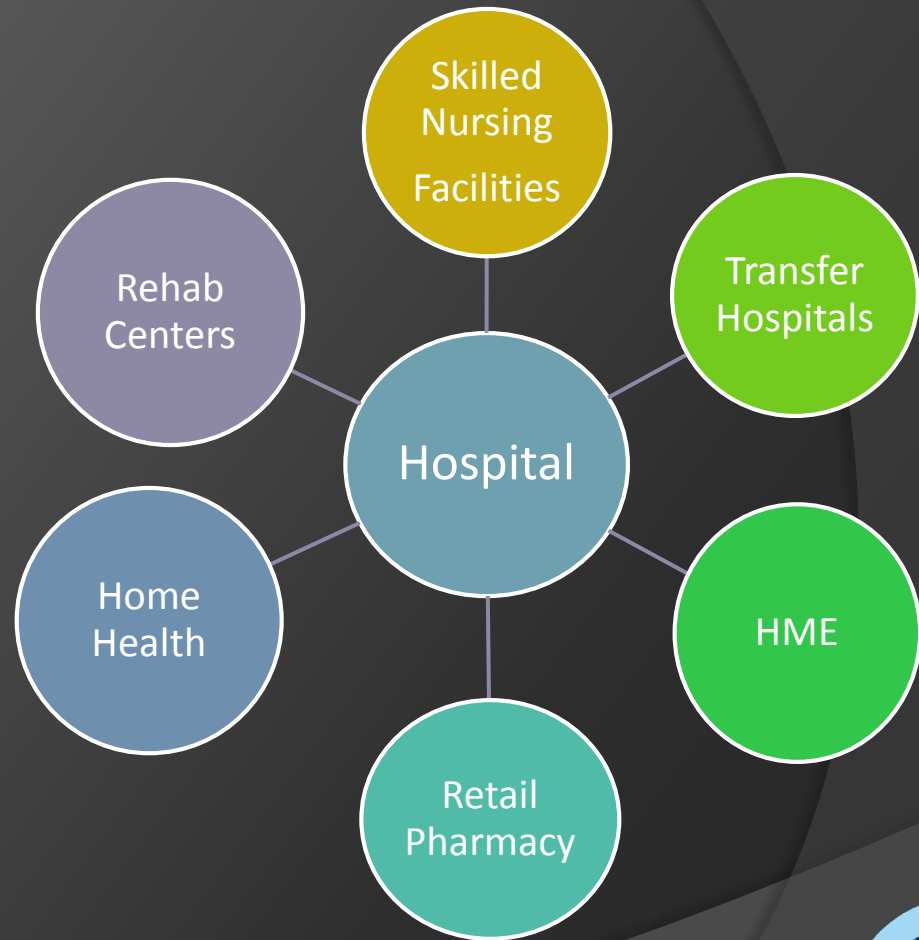
Supply Chain Readiness

- Include distributors and suppliers in planning meetings
- Share demand estimates
- Communicate “Go-Live” date
- Establish lunch & Learn or other educational sessions



External Provider Team

- Include both owned and external care sources teams in planning
- Discuss supply readiness
- Communicate “Go Live” date
- Identify training opportunities



Mercy Medical Center Des Moines

- Risk Assessment
- Develop a Cross functional Team
- Develop a plan for education, product change alerts, online learning hands on, floor to floor rounding
- Trial product in the NICU prior to implementation
- Lessons Learned



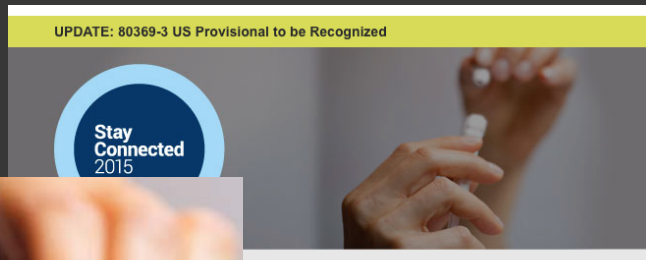
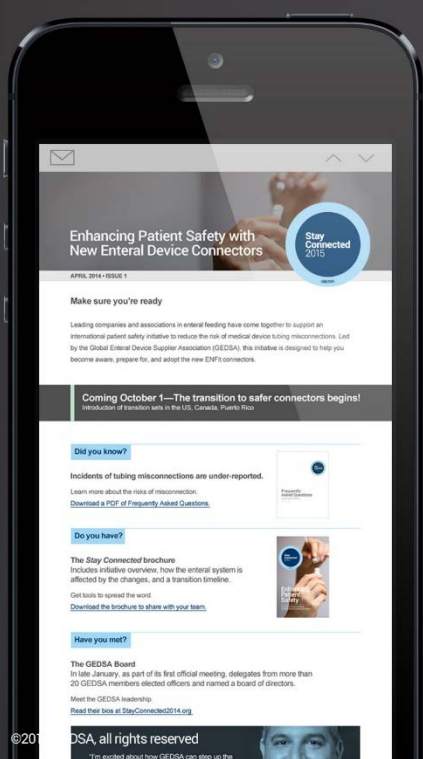
Recommendations

- ◉ Work with your Cross Functional Team within your provider system
 - Determine the transition plan and timing that meets your needs
 - Partner with your suppliers and include them in your regular meetings
- ◉ Work with your Supplier Representative:
 - Understand what products are available and when
 - Item Number Changes? – Obtain Crosswalk (current to ENFit item numbers)
 - Consider all components and accessories to feeding system
- ◉ Syringes:
 - Key components to ENFit Transition
 - Smaller sizes (< 3mL, possibly 5mL) should have an ENFit Low Dose Tip
 - Verify adequate supply to meet your needs
 - Consider a second and possibly third supplier
- ◉ Stayconnected.org
 - Sign up for our newsletter to stay on top of any updates, changes, and news



Brochures, Presentations, FAQs & Checklists

www.stayconnected.org



American National Transition Checklist for Facilities and Institutions

A new design standard for medical device tubing connectors is on its way. Starting with enteral feeding and the new ENFIT connectors, application-specific standards will help ensure that connectors do not fit into ports other than the type for which they are intended, reducing the incidence of misconnections.

This global patient safety initiative starts in the US, Canada, and Puerto Rico, with the goal of completion in these markets by 2016.

4 Published

Hospitals, long-term care facilities, and other institutions will need to have a strong understanding of the changes and be able to disseminate that information across multiple groups within the organization. Please use the following STEPS to help your organization prepare for the impending changes:

S	Supplier communication	<ul style="list-style-type: none"> □ Familiarize yourself with all the product-specific changes coming from all the manufacturers that make up an enteral feeding system and their transition timeline
T	Training	<ul style="list-style-type: none"> □ Make sure all departments are aware of and prepared for the transition by communicating with leadership, holding talks and seminars, distributing department-specific checklists, and leveraging other communication tools your organization utilizes
E	Education	<ul style="list-style-type: none"> □ Understand that this change affects multiple functions within your organization □ Chief Medical Officer – Assess for changes needed in prescribing, tube placement, or documentation practices. □ Clinicians – Nurses, physicians, clinical nutrition staff, and other clinicians in all patient care areas where feeding tubes are placed or utilized will need to know what products are affected, how the new connectors work, and when they will change □ Pharmacy – Plan for storage of new products and changes to protocols and processes □ Supply Chain and Materials Management – Understand transition timing and plan for storage space in central supply, nursing units, and on the floor □ IT/informatics – Determine a plan if physician order sets need to change □ Risk Management – Understand impact of all the changes in order to help mitigate any problems
P	Process	<ul style="list-style-type: none"> □ Develop a multidisciplinary, institutional-wide team to help work through preparation, education, and implementation steps of this change that affects the entire enteral feeding system
S	Supply management	<ul style="list-style-type: none"> □ Maintain adequate supply without excess inventory, returns, or unnecessary waste

for the US Food and Drug Administration with this recognition, the regulatory pathway for all of this marks a significant step in the new ENFIT connector and Puerto Rico timeline

Questions

