Being Prepared: New Enteral Connectors

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Objectives

1. Explain why new enteral connector design standards are needed
2. Describe features of the new enteral connector standards and their safety implications
3. Outline the timeline for new connector design implementation and transition
4. Share blenderized diet testing data
5. Listen to concerns and questions from consumers and caregivers
What is a Small-bore Connector (SBC)?

A small-bore connector:
• inner diameter of less than 8.5 mm
• used to link or join medical devices, components, and accessories for the purpose of delivering fluids or gases.

A Luer connector is a classic type of a small-bore connector used commonly in the healthcare setting - a universal connector.
Enteral Misconnection

Definition: An inadvertent connection between an enteral feeding system and a non-ental system such as an intravascular catheter, peritoneal dialysis catheter, tracheostomy, medical gas tubing, etc.

Misconnections: Why is this important?

A 24-year-old woman was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready to hang enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, which the woman had received on previous admissions, pulled regular intravenous tubing from floor stock, spiked the bag, and started the infusion of tube feeding through the patient’s peripherally inserted central catheter line. The fetus died—and then the mother, after several hours of excruciating pain.

Enteral Misconnections: Contributing Factors

Human Factors

• Nursing or Caregiver Fatigue
• Distractions
• Poor Lighting

Physical and Design Factors

• Compatible tubing between unlike systems
• Luer connectors
• Use of IV syringes for oral meds
• Universal Spike for bags
Enteral Misconnection Events and Alerts
Enteral Misconnections: Published Cases

Invited Review

Tubing Misconnections: Normalization of Deviance

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Financial disclosure: none declared.

116 published cases as of 2011
Like most errors, highly under-reported
Enteral Misconnections: Points of Concern
Enteral Nutrition Connector Call for Design Changes

• Product manufacturers are urged to implement “incompatibility by design” features. ¹
• “Forcing function” design changes would make incorrect connections impossible.
• A physical barrier is the most effective preventive tool when inappropriate connections are attempted.
• The entire line of connections must be unique to prevent mistakes in connection.

The Joint Commission Sentinel Event Alert.
Who is ISO and Why Them?

• ISO: International Organization of Standardization
  • Is recognized by many countries, organizations and other entities as “THE” resource to drive conformity
    • Examples:
      • Luer fittings are an ISO standard 594
      • Syringes are in ISO standard 7886
  • As such, ISO sets voluntary global standards for various governments, purchasing organizations, manufacturers and users to subscribe to.
ISO 80369-1 SBC Master Standard

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements

Requirements:
- Not connectable with others in series
- Rigid or semi-rigid
- Misconnection test
- Not connectable with luer or needleless connector ports
New Enteral Feeding System
Opportunity: Patient Safe Enteral Connectors

**Solution:** Result of global collaboration including but not limited to government regulatory agencies, industry, quality improvement organizations and clinicians

**PHASE I**
New Enteral Connectors

Nutrition Source

Patient Access

Pending FDA approval of devices
Feeding Tube Functions

• Feeding Formula
• Hydration
• Flushing
• Medication Delivery
• Decompression
Nutrition End Connector

- Introduced in 2012
- Adopted across the market by enteral industry working together.
- Prevents that inadvertent use of IV tubing as an administration set.
- Will be an ISO standard soon.
Patient-Access End Connector

Timeline - One year transition

- October-December 2014 - administration sets
- December 2014-Q1 2015 enteral syringes
- Starting March 2015 - tubes
- Pending FDA approval of devices
Patient-Access End Transition Set (adapter)

• Allows fitment to current feeding ports until new enteral feeding tubes are available.
• Will be available with the administration set.
• Use during transition.
Patient-Access End Syringe

• Syringes to administer medicine, flushes, supplemental hydration, or bolus feeding through the enteral feeding tubes.

• Will require this specific syringe, can no longer use luer, oral, or cath-tip syringe to fit into new tubes.

• Available end of 2014-early 2015
Communication: Partnership Between Industry, Clinicians and Other Stakeholders

- GEDSA also organizing Core group of clinical and supply organizations: A.S.P.E.N.,FDA, TJC, AAMI, Premier Safety, Novation, CMS
Summary

• Get the Facts - Access the FAQs
• Become a champion for change
• Go back and form awareness groups including all stakeholders
• Watch for educational offerings
• Go to www.StayConnected2014.org
• EN Safety Campaign: A.S.P.E.N. Website www.nutritioncare.org/ENToolkit
Blenderized Diet Testing Protocol & Data Review
Test Protocol Purpose

• Determined the flow rate of blenderized diet formulas through various available feeding tube components and systems
• Emphasis on comparing current Kimberly-Clark feeding tube systems with those with a proposed ENFit connector system.
• Protocol was for information gathering only.
• No acceptance criteria was established.
Test Protocol Scope

• This protocol applies to the following Kimberly-Clark feeding tube systems:
  • Low profile feeding tube system with “Bolus” extension set
  • G-Tube – Silicone balloon retained feeding tube
  • PEG – Initial placement feeding tube with solid silicone bolster and attachable feed head
  • GJ– Dual lumen, balloon retained, Jejunal feeding tube with gastric decompression lumen
• All systems listed above were tested with current “funnel” type feeding connections and also the ENFit (ISO 80369-3 compliant) connection system
• Testing was performed with commercially available viscous formulas, water, applesauce and samples of a blenderized diet. All fluids were meant to replicate what is used in practice.
• Testing used 18fr/20fr large bore tubes
Test Types

• Viscosity measurements – measured the formula at two different settings to determine viscosity and shear thinning (or thickening) characteristics.

• Pressure testing – determine how much pressure was required to dispense formulas through a 60ml syringe (Catheter tip & ENFit)

• Gravity Flow – Formulas were allowed to flow through a feeding tube system with a minimal (18”) pressure head.
Viscosity Comparisons @ 25°C (mPa*S)

<table>
<thead>
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<th></th>
<th>Low</th>
<th>Med</th>
<th>Max</th>
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<tbody>
<tr>
<td>Water</td>
<td>2.5</td>
<td>52.5</td>
<td>6616</td>
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<tr>
<td>Commercial 1.2 cal elemental</td>
<td>12000</td>
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<td>Applesauce</td>
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<tr>
<td>Blenderized</td>
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Pressure Test Fixture

- Test Fixture Grips
- Support Structure
- 60ml Syringe
- Adapter (if needed)
- Feeding Tube

Kimberly-Clark Confidential
MIC-KEY 20fr x 5.0cm

**Force (lbf) to dispense @ Room Temperature (22 - 23°C)**

- **Water**
  - Start: Cath Tip, ENFit
  - Mid: Cath Tip, ENFit
  - End: Cath Tip, ENFit

- **1.2 kCal Formula**
  - Start: Cath Tip, ENFit
  - Mid: Cath Tip, ENFit
  - End: Cath Tip, ENFit

- **Applesauce**
  - Start: Cath Tip, ENFit
  - Mid: Cath Tip, ENFit
  - End: Cath Tip, ENFit

Kimberly-Clark Confidential
Force (lbf) to dispense @ Room Temperature (22 - 23°C)

Japan (Meiji)

Blenderized at 4°C

Blenderized at Room Temp.
Balloon G-Tube – 20fr

**Force (lbf) to dispense @ Room Temperature (22 - 23°C)**

- **Water**: 1.2 kCal
- **1.2 kCal Formula**: 1.2 kCal
- **Applesauce**: 1.2 kCal

![Graph showing force to dispense for different substances](image-url)

- **Cath Tip** and **ENFit** forces are compared for different stages (Start, Mid, End) for each substance.
Balloon G-Tube – 20fr

Force (lbf) to dispense @ Room Temperature (22 - 23°C)

- Japan (Meiji)
- Blenderized at 4°C
- Blenderized at Room Temp.

Not Tested

Kimberly-Clark Confidential
Standard PEG – 20fr (10” length)

**Force (lbf) to dispense @ Room Temperature (22 - 23°C)**

<table>
<thead>
<tr>
<th></th>
<th>Water</th>
<th>1.2 kCal Formula</th>
<th>Applesauce</th>
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</thead>
<tbody>
<tr>
<td><strong>Start</strong></td>
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<tr>
<td><strong>Mid</strong></td>
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<td><img src="image2" alt="Graph" /></td>
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<tr>
<td><strong>End</strong></td>
<td><img src="image1" alt="Graph" /></td>
<td><img src="image2" alt="Graph" /></td>
<td><img src="image3" alt="Graph" /></td>
</tr>
</tbody>
</table>
Standard PEG – 20fr (10” length)

Force (lbf) to dispense @ Room Temperature (22 - 23°C)

- Japan (Meiji)
  - Cath Tip
  - ENFit

- Blenderized at 4°C

- Blenderized at Room Temp.
  - Not Tested

- Force (lbf) to dispense:
  - Start: Cath Tip 4, ENFit 6
  - Mid: Cath Tip 8, ENFit 8
  - End: Cath Tip 4, ENFit 6

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GJ – 18fr x 45cm (Gastric Lumen)

**Force (lbf) to dispense @ Room Temperature (22 - 23°C)**

<table>
<thead>
<tr>
<th></th>
<th>Water</th>
<th>1.2 kCal Formula</th>
<th>Applesauce</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>Cath Tip</td>
<td>ENFit</td>
<td>Cath Tip</td>
</tr>
<tr>
<td>Mid</td>
<td>Cath Tip</td>
<td>ENFit</td>
<td>Cath Tip</td>
</tr>
<tr>
<td>End</td>
<td>Cath Tip</td>
<td>ENFit</td>
<td>Cath Tip</td>
</tr>
</tbody>
</table>

Kimberly-Clark Confidential
GJ – 18fr x 45cm (Gastric Lumen)

Force (lbf) to dispense @ Room Temperature (22 - 23°C)

- Japan (Meiji)
- Blenderized at 4°C
- Blenderized at Room Temp.

Force (lbf) to dispense for Cath Tip and ENFit across Start, Mid, and End:

- Japan (Meiji): Cath Tip (Start: 10, Mid: 15, End: 20), ENFit (Start: 15, Mid: 20, End: 25)
- Blenderized at 4°C: Cath Tip (Start: 20, Mid: 25, End: 30), ENFit (Start: 25, Mid: 30, End: 35)
- Blenderized at Room Temp.: Cath Tip (Start: 25, Mid: 30, End: 35), ENFit (Start: 30, Mid: 35, End: 40)

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GJ – 18fr x 45cm (Jejunal Lumen)

Force (lbf) to dispense @ Room Temperature  (22 - 23°C)

- **Water**:  
  - Start: 1 lbf, Mid: 1 lbf, End: 2 lbf

- **1.2 kCal Formula**:  
  - Start: 10 lbf, Mid: 15 lbf, End: 12 lbf

- **Applesauce**:  
  - Start: 15 lbf, Mid: 20 lbf, End: 18 lbf

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GJ – 18fr x 45cm (Jejunal Lumen)

Force (lbf) to dispense @ Room Temperature (22 - 23°C)

Japan (Meiji)
Blenderized at 4°C
Blenderized at Room Temp.

Cath Tip  |  ENFit
Start    |  Mid  |  End

Cath Tip  |  ENFit
Start    |  Mid  |  End

Cath Tip  |  ENFit
Start    |  Mid  |  End

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Gravity Flow Test Fixture / Set-up

Set-up 1
MIC-KEY with Extension Set

Set-up 2
G-Tube

Set-up 3
PEG Tube

Set-up 4
TJ-Tube

Catheter Tipped Syringe

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Gravity Flow Comparison, Water

ml/minute @ Room Temperature (22 - 23°C)

- GJ - Jejunal
- GJ - Gastric
- PEG
- G-Tube
- MIC-KEY

ENFit vs. Cath Tip

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Gravity Flow Comparison,
1.2 kCal Formula
Gravity Flow Comparison, Blenderized

<table>
<thead>
<tr>
<th>Device</th>
<th>ENFit</th>
<th>Cath Tip</th>
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<tbody>
<tr>
<td>GJ - Jejunal</td>
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<tr>
<td>GJ - Gastric</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEG</td>
<td></td>
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</tr>
<tr>
<td>G-Tube</td>
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<td></td>
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</table>

mil/minute @ Refrigerated conditions (≈ 4°C)
Conclusion

• Blenderized formulas are not all the same and tubes vary as well.

• In this study, with these tubes and formulas, ENFit and Cath-tip syringes flow and pressure requirements were essentially equivalent.

• If your formula goes through the cath-tip syringe, it should go through the ENFit connector.

• It is recommended that each company perform testing on its own line of tubes with a variety of formulas.