Navigating the New ISO Connectors and How it Will Affect HEN Patients

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Disclosures

• Nestle- consultant
• Metagenics- consultant
• NIH- NIDA
Objectives

• Describe the new enteral tube connectors
• Evaluate the reason why we need new connectors
• Examine how this new change will affect HEN patients and loved ones
  • Blenderized tube feeds
  • Venting
  • Medication delivery
Why a new connector?

- A typical patient could be connected, via tubes or catheters, to several delivery systems
- Tubing misconnections refer to what happens when a tube from the medical device for one delivery system is connected to a system that serves a completely different
- Example from Mayo: RN flushed the balloon port causing the balloon to rupture, tube fell out.
• Earliest case of misconnection 1972
  • Cow’s milk intended to be given in the stomach accidently given IV
  • Patient survived the hypersensitivity event but had a coagulopathy

• 116 other cases of misconnection identified
  • 21 deaths, Numerous other serious consequences reported

• Joint Commission has recognized the serious nature of misconnections
GEDSA


The Global Enteral Device Supplier Association (GEDSA) was formed to help introduce international standards in medical device tubing connectors, which will enhance patient safety. Our connections will facilitate a stronger flow of communication to raise awareness and encourage adoption.
New connectors

• Reducing the risk of misconnection requires a complete design change with correlating standards established and adopted across the industry and around the globe.

• Enteral devices are the first of all the clinical applications to undergo this change.

• GEDSA and manufacturers have teamed together to make this happen.
Transition piece

Patient end has hole, nutrition end is open.

New connection
Transition Timeline

• First quarter 2015 - Transition sets available in US
• First quarter 2016 - Enteral-specific syringes available in US
• First quarter 2016 - New enteral feeding tubes the ENFit connector available in US
• January 2016 - California mandate takes effect
• 2017 - Transition to ISO connectors complete
Standardization
• RCT 7 ICUs in France

• Adults requires arterial line, CVC or both for > 48 hours

• Randomized to either Biopatch vs standard dressing

• Major Clinical Relevant Infections

  Infections decreased by 49%!!
  • Biopatch 10/1953
  • Placebo 19/1825

• 8 patients severe contact dermatitis

Timsit JF et al. 2009 JAMA; 301(12);1231-1241
Chlorhexidine Gluconate–Impregnated Central Access Catheter Dressings as a Cause of Erosive Contact Dermatitis

A Report of 7 Cases

Nicole A. Weitz, BA; Christine T. Lauren, MD; Jessica A. Weiser, MD; Nicole R. LeBoeuf, MD; Marc E. Grossman, MD; Katherine Biagas, MD; Maria C. Garzon, MD; Kimberly D. Morel, MD
How New Connections Impact HEN Patients

- Blenderized Tube Feeding
- Venting
- Medications
GEDSA and BTF

The ISO 80369-3 enteral feeding design standards were developed with current practice in mind and specific requirements to avoid any disruption of therapy. The bore size (or hole) in the ENFit connector was designed to be consistent with the current connector (commonly called “Christmas tree” or “stepped adapter”). Therefore, feeding through devices with the ENFit connector is intended to be consistent with current practice. For more information, contact the manufacturer of the enteral device directly.
Blenderized Tube Feeding

- Has been used since tubes were first put in
- There are a few studies raising concerns about the safety of BTF in the hospital
- HEN pediatric studies show a benefit
- Studies lacking in HEN adults
BTF
Safety and Nutrient Content

• Hospital prepared BTF had unacceptable levels of contamination\textsuperscript{1,2,3}

• Wide variance in calorie, protein and micronutrient content\textsuperscript{3,4}


ASPEN Recommendations
Nutrition Support for Home and Alternate Site Care

• “EN formulations shall be prepared to prevent contamination. Commercially available EN formulations shall be used whenever possible.” (15.1)\(^5\)

• “The use of home blenderized or reconstituted powered EN formula requires additional safe food handling and storage practices.” (18.4)\(^5\)

Blenderized Feeds
<table>
<thead>
<tr>
<th>Concern</th>
<th>Blenderized</th>
<th>Commercial Enteral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination</td>
<td>Likely</td>
<td>Unlikely</td>
</tr>
<tr>
<td>Consistent nutrient delivery</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Suitability for volume-</td>
<td>Hard to prepare as high-density nutrition</td>
<td>Available at high-calorie densities</td>
</tr>
<tr>
<td>sensitive patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeding tube flow</td>
<td>Poor flow with gravity feeding or with pump</td>
<td>Few or no flow problems</td>
</tr>
<tr>
<td>Tolerance and immune function</td>
<td>No special ingredients</td>
<td>Available with tolerance-promoting or other pharmaconutrients</td>
</tr>
</tbody>
</table>
In some parts of the world, for economic and cultural reasons, hospital staff members still blenderize foods to make tube-feeding mixtures in some hospitals. Such feedings are thought to be naturally healthy and economical; study results reveal that neither belief is true.
Average Temp in the Hospitals in the Philippines 79-88 degrees F

Senior author worked for Industry
WHAT DO NUTRITION EXPERTS SAY ABOUT BLENDERIZED FEEDS?

According to European experts on clinical nutrition, blenderized enteral feeds may be necessary when ready-to-use liquid or hydrated powdered formulas cannot be obtained, as during natural catastrophes. Such feedings can be delivered by way of nasogastric or gastrostomy tubes to the stomach where acid provides some natural decontamination; infusion into the duodenum or jejunum is discouraged due to safety concerns.
HEN BTF in Pediatrics

• Shown to be effective for reflux
• No problems with safety or food borne illness

Mayo HEN Program

- Program started in 1985
- Train 700 HEN patients per year
- Have trained over 12,000 since program started
- Patients have told HEN team members for years they have used BTF at home
• Designed a cross sectional study to evaluate the prevalence and frequency of BTF use in the Mayo adult HEN population
Methods

- Survey given at follow up in the HEN clinic
- Prospective cross-sectional study (n=54).
- Inclusion criteria: age ≥ 18 years
- HEN ≥ to 3 weeks
- Prescribed commercial enteral formula.
- Gastrostomy feeding tube
- Survey time: 6 months
BTF Survey

- 15 Question BTF Survey
- Validation
  - Expert validation HEN team
  - 10 HEN experienced patients
Demographics Results

- Ambulatory care (outpatient clinic)
- Mean age: 58.9 +/- 13.7 years
- 31 (57.4%) male
- 23 (42.6%) female
- 38 (70.4%) not working or retired
- 12 (22.2%) working part time
- 4 (7.4%) working full time
Use of BTF in Mayo HEN Adults

• 55% used BTF in varying amounts
Use of BTF in Oley Consumers

• 80% used BTF in varying amounts
Frequency of BTF

Figure 2. The number of days per week patients use blended tube feeding.
Why use BTF?

- I have food allergies 2 (5%)
- It makes me feel “normal” 9 (24%)
- I don’t like the ingredients of commercial formulas 9 (24%)
- I can tolerate it better 11 (30%)
- I like eating what my family eats 12 (32%)
- It is more natural 17 (46%)
- Other 6 (16%)
### Self-reported symptoms on BTF and commercial tube feedings

<table>
<thead>
<tr>
<th>Symptom</th>
<th>While using BTF</th>
<th>While not using BTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptoms</td>
<td>25 (68%)</td>
<td>16 (43%)</td>
</tr>
<tr>
<td>Weight Loss</td>
<td>6 (17%)</td>
<td>10 (33%)</td>
</tr>
<tr>
<td>Gas/ Bloating</td>
<td>6 (16%)</td>
<td>9 (24%)</td>
</tr>
<tr>
<td>Nausea/ Vomiting</td>
<td>4 (11%)</td>
<td>3 (8%)</td>
</tr>
</tbody>
</table>
Conclusions

• BTF appears to be used in the majority of Mayo HEN patients
• Self reported symptoms do not appear to be different BTF vs Commercial formula
• Open Label Pilot to test safety
• RCT to compare BTF with Commercial Formula
EnFit and BTF

• In response to questions raised in LifelineLetter May/June GEDSA, Kimberly-Clark, ASPEN Tested BTF and EnFit

• Tested commercially available BTF, applesauce, standard formula, and Japanese formula

• Concluded that flow pressure essentially equivalent EnFit and Cath Tip

• If your formula goes through the cath tip syringe it should go through the EnFit
EnFit and BTF

- Prototype EnFit
- Observations that Mayo BTF would not pass through EnFit
- Tested the two commercially available BTFs, standard formula, versus a mayo prepared BTF
- Force measure in Mayo Physiology lab
<table>
<thead>
<tr>
<th>Cath Tip</th>
<th>EnFit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Jevity 1.5</strong></td>
<td>10N to start, steady 10N for 30 seconds</td>
</tr>
<tr>
<td><strong>Liquid Hope</strong></td>
<td>15N to start, 14N to flow 30 seconds</td>
</tr>
<tr>
<td><strong>Real Food Blend</strong></td>
<td>23N to start, steady at 23N for 30 seconds</td>
</tr>
<tr>
<td><strong>Mayo BTF</strong></td>
<td>30N to start, steady at 30N</td>
</tr>
</tbody>
</table>
Conclusions

• Mayo BTF will pass through Cath-Tip but not pass through EnFit
• Commercially available BTF will pass through both
• None of our patients surveyed used commercially available BTF
• Testing from Non-GEDSA, ASPEN, or Industry sources should be done to ensure BTF can be used with the new connectors
How New Connections Impact HEN Patients

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- Venting
- Medications
GEDSA and Venting

Venting will work in the same manner. Venting a feeding tube with the new standard ENFit connector will require a syringe with the new ENFit connector.
Venting

Figure 4. Draining using a syringe

Figure 5. Drainage using a leg bag

Figure 6. Draining using a gravity bag (at night)
How New Connections Impact HEN Patients

- Blenderized Tube Feeding
- Venting
- Medications
GEDSA and Medications
Mayo and Meds

- Tested a number of medications crushed
  - Nexium, tums, metoprolol, tylenol
- No difference in flow through the EnFit vs Cath Tip Syringe
Mayo and Meds

- Problems with EnFit centered on the ability to evacuate the crushed med mixture completely compared to Cath Tip Syringe
GEDSA Smaller hole and feeding

Q. Will the smaller size of the hole leaving the syringe impact ability to feed?

A. These enteral-specific syringes with the new ENFit connector will likely have a smaller hole than the catheter-tip syringe. However the hole will not likely be smaller than the patient access end of the (bolus) extension set opening on most low-profile devices. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration. For other devices, the industry is currently evaluating the impact of a smaller size of the hole.
Conclusions

• Misconnections with EN delivery devices have caused harm and even death to patients

• GEDSA and industry have developed a EN delivery device that will not connect to other delivery systems which is very positive

• There may be some problems with the EnFit and BTF which over 50% of our patients use

• There are still answers to questions about EnFit and medications and venting
Questions?