Reducing the Risk of Medical Device Tubing Misconnections

Oley Update – 7/6/16
Topics for Discussion

- Background
- Timing & Implementation Logistics
- Dose Accuracy
- Blenderized Tube Feeding
- Recommendations
- Reporting Adverse Events
- Questions
MISSION

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

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## Supporting Organizations

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<td>HEALTHTRUST®</td>
<td>ISMP</td>
<td>The Joint Commission</td>
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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.

- **Feeding tube to a tracheostomy tube**, delivering milk into an infant’s lung, resulting in death.

- **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 80369
Small-bore connectors

Technical Experts
Clinical Experts
Regulatory/Standards Experts

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ISO Design standards developed for system-specific applications

80369 Series
-1 General requirements

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<th>Urological</th>
<th>Limb Cuff</th>
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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
Significant Testing Conducted to Verify & Validate Enteral Standard Design

**Testing & Assessments**

- Clinical Assessment - 20 Physicians, Nurses & Pharmacists
- Usability/Human Factors - 53 Clinicians (including 15 NICU)
- Misconnections Assessment
- Syringe Accuracy Report
- User Survey – 35 respondents in 3 European markets
- Acceptability and Suitability Study - 48 Clinicians in 6 European markets
- LDT Syringe
  - Performance Testing
  - Usability Testing – 140 respondents in 8 countries
  - Misconnection Risk Assessments
- Reverse orientation usage – UK reverse Luer
  - Millions of patients over nearly 6 years without a reported event
Design standards for system-specific applications start with enteral

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Introducing ENFit, the proposed new ISO 80369-3 design standard connector

CURRENT

Male Stepped or “Christmas Tree” Connector from Administration Set

Female ENFit Connector from Administration Set

NEW

Female Feeding Tube Port

Male ENFit Connector for Feeding Tube

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GOAL: Eliminate the Long Term Need for adapters

TRANSITION SET
ENFit Transition Connector
• Temporary fitment
• From new ENFit connector to current feeding port

Check with your supplier regarding Transition Connectors from ENLock to ENFit
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

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**SYRINGES**
From oral, catheter, or Luer tip to enteral-specific fitment:
- Administer Medicine
- Flush
- Hydrate
- Bolus Feed

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Topics for Discussion

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GEDSA Members have confirmed their commitment to ENFit and the introduction of syringes and feeding tubes in 2016.
Variations in Enteral Feeding Point of Care that Affect Adoption/Implementation

- Acute Care (AC)
- Home Care (HC)
- Long Term Care (LTC)
- Other Countries
- Other States
Complications of Supply Chain

- Inventory Levels
- Connectivity Between Suppliers
- Additional Issues
  - Changing Product Codes
  - Excess and Obsolescence
  - Returns
Complexities in Supply

Component Manufacturing

Shipping

Finished Goods Manufacturing

Manufacturer/Supplier Distribution Centers

AC, LTC or HME Warehouse

Distributor Warehouse

Est. Inventory in Supply Chain
14-34 Weeks

Est. Transition Lead Time
6 – 12 Months

4-8 Weeks

1 Week

2-4 Weeks

4-12 Weeks
Topics for Discussion

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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 ± 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*
Dose Accuracy of ENFit® Low Dose Tip vs. Common Enteral/Oral Tip Syringes

% Dose Accuracy (95% CI)

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe.
Low Dose ENFit® 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:
The FDA has thoroughly reviewed and cleared two 510(k) submissions for ENFit Low Dose Tip Syringes
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Third Party Flow Rate Testing

Goal
• Establish impact of ENFit™ Connector on feeding tube performance and characterize current user practices with regard to blenderized tube feeding BTF

Mayo Clinic (Rochester, MN)
• Ryan Hurt, MD; Manpreet Mundi, MD; Lisa Epp, RD
• Flow rate comparison (Legacy vs. ENFit) using commercial formulas

FDA
• Suvajyoti Guha; Josh Silverstein
• Flow rate comparison (Legacy vs. ENFit) confirmation of Mayo testing and characterization of BTF use
• Force testing comparison

GEDSA and Oley supporting with products and review of protocols only
BTF Home User Questionnaire

• Create a validated, objective data base that can be used for publication, input into standards and decision making

• Builds on Mayo/Oley survey to identify home tube feeding practices
  • Survey focused on attitudes about BTF, but execution created bias in results
  • Nothing on product use (critical GEDSA concern)

• Summary
  • Demographics of home tube fed patients
  • Commercial vs. BTF use
  • Basic questions on reimbursement
  • Tube Clogging concerns
  • BTF practices such as – equipment, foods used, motivation, challenges with current devices, how made
BTF Testing Will Lead to...

- Define a problem if there is one
- Recommendations & Best Practices
- New Indications for Use
- Modified Connectors?
- New Devices?
- Others Solutions
Manufacturers Maintaining Legacy Devices

Cook Medical Representative...
“We have not set a date to discontinue legacy devices and still offer these devices as an enteral option”
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Recommendations

- Work with your Home Health/Infusion Suppliers:
  - Prepared?
    - No, reach out to GEDSA and stayconnected.org
    - Yes, understand specific ENFit Transition Timing for all tubes and syringes
  - Make sure they have the right components you need

- Syringes:
  - 5mL and below should consider a Low Dose Tip
  - 6mL and above should not require a Low Dose Tip
  - Verify adequate supply to meet your needs

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  - Sign up for our newsletter to stay on top of any updates, changes, news
Brochures, Presentations, FAQs & Checklists all at www.stayconnected.org

New global design standards for medical device tubing connectors

Enhancing Patient Safety

Provisional American National Standard Published

AAMI/ICN3 (PS): 2014 Published

The Association for the Advancement of Medical Instrumentation (AAMI) published AAMI/ICN3 (PS): 2014 on Friday, December 12, 2014. This US provisional standard is a result of the work completed on the second Draft International Standard (DIS) 80369-3 through the International Organization of Standardization (ISO) process. With the adoption of ISO 80369-3, the US provisional standard will be replaced by a parallel adoption of ISO 80369-3 and the text will be aligned to the ISO standard.

The next step in the process is for the US Food and Drug Administration (FDA) to recognize this US Provisional Standard. Along with this recognition, the FDA also intends to provide additional guidance and assist in a clear regulatory pathway for all manufacturers impacted by the ISO 80369 small bore connectors. This marks a significant step forward in the introduction of new, safer connectors starting with the new ENFit connector external administration sets in Q1 2016. Click here for the US, Canada, and Puerto Rico timeline and additional details on the introduction.

Transition Checklist for Facilities and Institutions

A new design standard for medical device tubing connectors is in the works. Starting with local feedback and the new ENFit connector, applications across the hospital will help ensure that connectors do not remain proprietary. Evaluate where the points in the chain are that are being recognized, and the benefits of transitioning to a global standard. This global patient safety initiative starts in the US, Canada, and Puerto Rico, with the goal of completion on these models by 2017.
Topics for Discussion

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Reporting an Adverse Event

- Reach out to the manufacturer customer service via phone or email.
- Each manufacturer may have a different procedure for handling the complaint but have the same obligation to keep track of and investigate a complaint.
- Contact information can be found on the company website.
- Common information you will need when you contact the company:
  - Patient age, gender, and medical condition
  - Clear and detailed description of event
  - List of all devices relevant to the event
  - Product identifiers like brand name, model and lot number
Reporting an Adverse Event to the FDA

- Send report to FDA via on-line report form (& instructions) accessible at:
  - Form 3500A (mandatory report)
  - Form 3500 (voluntary report for practitioners/physicians)
  - Form 3500B (voluntary report for consumers/patients)

- Phone FDA at: 1-800-FDA-1088; or

- Download the form and mail to the address on the form

- Facilities that are subject to FDA’s user facility reporting requirements should follow the reporting procedures established by their facilities.
QUESTIONS?
Questions:
- How will people vent with an ENFit connector?
- People are concerned that they will not be able to vent through the G portion of a G-J tube. Is that a legitimate concern?

Answers:
- Device specific performance Issue.
- Most common G-J tubes inner diameters will not change and therefore performance will not be negatively impacted
Cleaning

**Question:**
How will consumers keep ENFit connectors clean?

**Answers:**
- A reverse system with a very similar design has been in place in the United Kingdom resolved by proper tube maintenance and flushing.
- When flushing with a syringe, keep final 0.5 inch (centimeter) of the tubing or syringe free of formula.
- There are already products being promoted for the cleaning of the ENFit connectors.
- ASPEN will be issuing guidance on proper cleaning techniques including the use of household swabs (ie. Q-Tips)
Clogging

Question:
- Clogging is always a big problem with feeding tubes. Do you anticipate more clogging with a smaller-bore connector?
- Many are concerned that their tubes will need to be replaced more often, either because a clog or tube gets dislodged (pulled out) accidentally.

Answers:
- Clogging would be a device specific performance attribute.
- ISO Requirements specify a forcing function and prefer a locking feature.
- The risk inadvertent disconnections, a common complaint from tube fed patients and caregivers, will be lower with the ENFit system due to the interlocking design.
Dear Valued Customer,

Important Update Regarding the Availability of ENFit™ Connectors

This letter is to provide an update on the status of the heightened concerns with the proposed ISO 80369-3 ENFit™ design, and to reinforce BD's continued commitment to manufacture safe and reliable oral and enteral syringes.

Over the past several months, BD has been working closely with the healthcare community to better understand these concerns and to share them with the broader industry. However, due to fundamental differences in the approach to delivering a safe ENFit™ solution that works for all patients groups, BD has withdrawn from the Global Enteral Device Suppliers Association (GEDSA), effective September 19, 2015.

Please contact your local BD representative should you have questions regarding this matter.

Sincerely,

Martin Jacobsen, M.Sc. (Econ.)
Senior Global Product Manager, WW Anesthesia & Enteral