Stay Connected
Enteral Feeding Device Connector Changes...Introducing ENFit
Learning Objectives

• Outline the background of Tubing Misconnections issue

• Explain why new small bore connector design standards are needed

• Describe features of the new enteral connector standards and their safety implications

• Plan the timeline needed to effectively implement and transition new connector design

• State supply chain efforts needed to increase awareness among end user
Tubing Misconnections Background

• Tubing misconnection errors are a critical and under-reported issue in health care organizations occurring with significant frequency and can lead to deadly consequences

• Misconnections occur when medical device tubing is unintentionally attached to tubing that performs a completely different function. Misconnections are attributed to the presence of universal connectors that allow fitment between physiologically incompatible systems

• To reduce the frequency of small bore connector hazards, the FDA is collaborating with the International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop the ISO 80369 standards

• Published in December, 2010, the ISO 80369-1 provides general requirements for small-bore connectors for liquids and gases in healthcare applications and establishes a framework for testing connectors to ensure non-inter-connectability.

• ISO design standards for non-Luer compatible connectors including Respiratory, Enteral, Urological, Limb Cuff Inflation and Neuraxial applications are under development with new connectors reaching the healthcare community early 2015

• California Senate Bill No.158: “Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for…” Assembly Bill 1867 delayed the effective date to for hospitals and suppliers to January 1, 2016
What is a Small-bore Connector (SBC)?

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**.

Slides courtesy Peggi Guenter, PhD, RN, FAAN Senior Director for Clinical Practice, Quality and Advocacy A.S.P.E.N.

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The Luer Connector

- Designed to attach hypodermic needles to glass syringes
  - 1896 by the H. Wulfing Luer Company
- A male and a female component are joined to form a secure yet detachable leak-proof connection

- International Organization for Standardization (ISO)-594
  - Current standard is vague: “conical fitting with a 6% taper for syringes, needles, and certain other medical equipment.”

- Luer connectors are used worldwide to connect:
  - Needles to syringes for injections
  - IV fluids to IV catheters
  - Enteral formulas to feeding tubes
  - Medication infusions to epidural catheters
How do tubing misconnections happen?

• A typical ICU patient may have as many as 40 connectors
  • Beaumont PICU identified 165 connectors in inventory
• Making tubing connections is a common, routine task
  • Clinicians may make up to 400 connections per day
• Many fluids in tubing look similar or are same color
• Clinicians are humans - humans make errors
  • Recurrently & predictably
  • Especially when in ‘automatic mode’
• Universal connectors allow misconnections between unrelated systems

Photo courtesy of Beaumont Hospital
Stayconnected2015.org
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

• connection of a **feeding tube to a tracheostomy tube**, delivering milk into an infant’s lung, resulting in death

• an **epidural infusion set connected to a peripheral IV**, delivering epidural medication to bloodstream, resulting in patient death

• a **feeding tube connected to an in-line ventilator suction catheter**, delivering feeding contents into the patient’s lungs, resulting in death

• a **patient’s heparin lock (peripheral IV route) connected to an automatic blood pressure cuff** by a family member, delivering air to the bloodstream, causing death

• a **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
Enteral Misconnection- How Can this Happen?

Obvious

Not so obvious

FDA Medical Device Safety Calendar, 2009
Definition of an Enteral Misconnection

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

Also known as a wrong route error or small bore misconnection

Enteral Misconnections: Contributing Factors

Human Factors
• Healthcare clinician fatigue
• Distraction
• Lighting

Physical and Design Factors
• Compatible tubing between unlike systems
• Luer connectors
• Use of IV syringes for oral meds
• Universal Spike for bags

Slides courtesy Peggi Guenter, PhD, RN, FAAN Senior Director for Clinical Practice, Quality and Advocacy A.S.P.E.N.
Enteral Misconnections: Published Cases

Invited Review

Tubing Misconnections: Normalization of Deviance

Debora Simmons, RN, MSN, CCRN, CCNS\textsuperscript{1,2};
Lene Symes, RN, PhD\textsuperscript{1}; Peggi Guenter, RN, PhD, CNSN\textsuperscript{3};
and Krisanne Graves, RN, MSN, CPHQ\textsuperscript{1}

Financial disclosure: none declared.

116 published cases as of 2011
Like most errors, highly under-reported
Enteral Misconnection Events and Alerts

TIMELINE: Enteral Misconnections

1972: First case report in literature, *The Lancet*

1979: Call for international enteral feed apparatus not compatible with IV lines

1983: Case report suggests incompatible connectors

1996: AAMI standard passed in 1996 with specific guidelines for feeding tubes—not liver lock compatible

2000: UK publication

2006: AAMI standard released

2006: ISMP

2007: ISMP

2008: ISMP

2008: ISMP

2009: ISMP

2009: JCAHO

2020: FDA

2007: Agency Alerts

* = Case Report

2017/07

@ D. Simmons & K. Graves

Slides courtesy Peggi Guenter, PhD, RN, FAAN Senior Director for Clinical Practice, Quality and Advocacy A.S.P.E.N.
Enteral Misconnections: Points of Concern
Impact of Tubing Misconnections

“When we got to the hospital, we were advised that Chloe’s G-tube line had been mistakenly attached to her IV line, causing my fortified breast milk to be delivered to her bloodstream. She was put on life support, suffered DIC, seizures and has various other medical problems, including documented neurological damage. It was the worst day of our lives.”

“My heart breaks daily, as I will never know her true potential...sadly, it was taken away from her that day. I don’t want what happened to our daughter to happen to anyone; it is totally preventable.”

Johannah Back
Chloe’s Mother

“We were informed by the surgeon and anesthesiologist in the case that the PACU RN at the surgery center hooked the BP monitor to my mother’s IV which caused the air embolus that killed her. I have been a RN for 30 years, worked Floor/CVICU/PACU, etc. and have never heard of such a thing.”

“I now feel a need to work tirelessly to educate others and work to eradicate such errors so another family does not have to suffer this incredible pain – I must do this for my mother.”

Tricia Otstot, RN
Daughter

“In all of these stories there are two sets of victims, the patient and family, as well as the clinician. Clinicians never mean to make these mistakes, but they do - because they can.”

Peggi Guenter, RN, PhD – ASPEN
October, 2013

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Extent of the tubing misconnection problem

• No mandatory reporting system
• Underreported event
  • A few hundred cases per year, estimated
• Various organizations have received reports, including
  • The Joint Commission
  • FDA
  • ISMP
• Many incidents / law suits settled – not reported
• First case report published in the literature, 1972
• Low incidence, but results in life-altering injury or death
Practice guidance, alerts have not solved problem

- **TJC - The Joint Commission**
  - Sentinel Event Alert, Issue 36

- **FDA - Food and Drug Administration**
  - Patient safety alerts, case studies, videos, letter to suppliers

- **ASPEN - American Society for Parenteral & Enteral Nutrition**
  - Clinical recommendations, education

- **CMS - Centers for Medicare and Medicaid**
  - Letter to surveyors to review hospitals prevention policies

- **AHRQ - Agency for Healthcare Research & Quality**

- **NQF - National Quality Forum**
  - Serious Reportable Events (Formerly called NEVER EVENTS)

- **ISMP - Institute for Safe Medication Practices**
  - Several medication safety alerts, self-assessment tool

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California Senate Bill No. 158

• California Senate Bill No.158: “Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for...”. Assembly Bill 1867 delayed the effective date to for hospitals and suppliers to January 1, 2016

• Published in December, 2010, the AAMI/ANSI/ISO 80369-1 provides general requirements for small-bore connectors for liquids and gases in healthcare applications and establishes a framework for testing connectors to ensure non-inter-connectability.

• In January of 2011, AAMI adopted the standard ANSI/AAMI/ISO 80369-1:2010:

• In order to meet this California deadline and transition healthcare institutions to new standard connectors, industry must introduce new connectors with a synchronized, phased launch to avoid unintended consequences and disruption of therapy
Drivers to Establish Small Bore Connector Standards

• Numerous reported deaths, severe harm or near misses following wrong route errors when oral liquid medicines, feeds, and flushes were administered intravenously and injuries being reported specifically from device misconnection incidences.

• WHO recognized this as a Global public health issue and requested to ISO for an industry standard.

• The Joint Commission guidance
  • Physical barriers (e.g. incompatibility by design) should be created to eliminate the possibility of interconnectivity between functionally dissimilar medical tubes and catheters to the extent feasible.
  • Industry-based standards and engineering design for medical tubes and catheters that are organ-specific or need-specific and do not interconnect should be established and promoted.

Excerpts from Patient Safety Solutions volume 1, solution 7  May 2007
Need for new connectors

• Prevention requires making wrong connections impossible
  • Changing design, shape, or size of the tubing connections

• Recommended solution
  • Creation of incompatible connectors
  • Connectors must be unique to product groups, but compatible across suppliers

• California legislation
  • Prohibits hospitals from using an epidural, intravenous or enteral feeding connector that fits into a connection port other than the type for which it was intended
  • Effective date January, 2016

• New standards for small bore connectors
  • Retain Luer connectors for hypodermic and IV applications
  • Develop unique connectors for each clinical delivery system
ISO TC 210 JWG4 Focus

Credit to the artist – Yan Nascimbene
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
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.

ISO 80369-1 General Requirements

• Published in Dec 2010; Recognized in the Federal Register (List 26) in March 2011.
• Intended as a reference document:
  • Provides the methodology, measures and procedures to prevent/reduce misconnection for new designs of small bore connectors.
  • Does not provide new designs
  • Does not specify requirements of devices intended to use new connectors w/in the ISO 80369 series.

• Materials – rigid/semi-rigid for all connectors within a connection.

• Non-interconnectable with each other and with those already standardized.
  • Determined by mechanical force function testing (annex B)

• Clause 7 – design acceptability w/in application – Human Factors and Usability

• Color/labeling not considered acceptable to reduce misconnection
Connector dimension allocation diagram

Exclusions: PG3: Cross assembled 2011-04-27 (M), Cross bag port 2011-04-27(F), Engage Cap S12-r00 (F), Engage Spike S16-r01(M), JMS 2011-04-01 (F), JMS 2011-04-01 (M)
PG6: Intervene Surety SpinalLok needle tip-V1 (M), Neuraxial lok4-r04(M), Vygon Neuraxial slip 2010-05-24 (M)
PG7: Luer Lock-r2 (F), Luer Lock-r2 (M), Needless-r2 (F)

as of June 11, 2011
Overlapping MAX/MIN ID and OD:

Within RESIDUAL INTERFERANCE or RESIDUAL GAP

No overlap or intended to connect

Possible Misconnection (RED)

Questionable (YELLOW) Or UNDEFINED

Non-connectable (GREEN) Or Designed to Connect
Sample Misconnection Assessment Chart
New Small Bore Connector Dimensions Proposal

When organized other bands would be available for other therapeutic areas

Current Luer would occupy this band
What About Color?

• Manufacturers have introduced color to try to trigger clinicians to prevent misconnections.
• However, color does not prevent the misconnection.
• Colors are not standardized across device types.
• May have a green connector for an EN device, an IV device, and a respiratory device so this defeats the purpose of color.
• Color is not required in the new connector standard.
FDA’s Current and Ongoing Efforts

• Active participation in development of the ISO standards

• Updated Tubing Misconnection Website:
  http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

• Recognition of ISO 80369-1 in the Federal Register (List 26) in March 2011

• July 2010 Letter to Manufacturers, Healthcare Professionals and Hospital Purchasing Departments

• Draft Guidance document for devices that contain small-bore connectors designed for enteral applications for Industry and FDA Review Staff
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm313382.htm

• Working with healthcare organizations to promote education of healthcare providers, users, and patients about this effort
FDA Future Plans for Compliance

• FDA is considering the best regulatory tools for implementation of these standards, such as:
  • Standards recognition
  • Guidance documents

• FDA will work with manufacturers to implement a regulatory pathway that will enable manufacturers to transition their devices to the new connector designs

• Any proposed regulatory pathway will be announced in the Federal Register for public comment in order to obtain feedback from all stakeholders

• FDA will provide guidance to manufacturers on whether there will be a set period of time for currently marketed devices to come into compliance with any proposed regulatory pathway

• FDA will provide guidance to manufacturers on the effect of the standards on currently marketed devices and new devices

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Stay Connected,
ENFit
&
Transition
to
Safer Connectors
4 Step and 3 Phased Approach

**Aware**
- Build awareness across the facility/provider to all impacted clinicians, administrators, supply chain and support staff.
- Communicate Who, What, Where, When, Why & How Impacted

**Prepare**
- Assess processes and protocols that may need to change
- Approve product changes and prepare materials/inventory mgt
- Train Clinicians and Materials/Inventory Management Staff
- Introduce new connectors into work stream to reduce tubing set misconnections and improve patient safety

**Adopt**
- Transition & Integration into medical practice
- Measure teams ability to adopt changes and reassess how to improve the process for next phase

**Measure**
- Post execution monitoring, metrics, feedback processes

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3 Phases of Delivery System Launches

**PHASE I - Enteral**

- Q1'14: AWARE Awareness Campaign
- Q2'14: PREPARE In-Service & Webinars
- Q3'14: ADOPT Product Launch & Implementation
- Q4'14: MEASURE Adoption & Adherence
- Q1'15: AWARE Awareness Campaign
- Q2'15: PREPARE In-Service & Webinars
- Q3'15: ADOPT Product Launch & Implementation
- Q4'15: MEASURE Adoption & Adherence

**PHASE II - Neuraxial**

- Q4'14: AWARE Awareness Campaign
- Q1'15: PREPARE In-Service & Webinars
- Q2'15: ADOPT Product Launch & Implementation
- Q3'15: MEASURE Adoption & Adherence
- Q1'16: AWARE Awareness Campaign
- Q2'16: PREPARE In-Service & Webinars
- Q3'16: ADOPT Product Launch & Implementation
- Q4'16: MEASURE Adoption & Adherence

**PHASE III – Therapeutic Family TBD**

- Q3'15: AWARE Awareness Campaign
- Q4'15: PREPARE In-Service & Webinars
- Q1'16: ADOPT Product Launch & Implementation
- Q2'16: MEASURE Adoption & Adherence
- Q3'16: AWARE Awareness Campaign
- Q4'16: PREPARE In-Service & Webinars
- Q1'17: ADOPT Product Launch & Implementation
- Q2'17: MEASURE Adoption & Adherence

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Future Enteral Feeding System

PHASE I
New Enteral Connectors

Nutrition Source

ENFit Patient Access

Pending FDA Clearance of Devices

Est. Q1 2015

Complete

Figure 3. Two-Piece Enteral Administration Set in Enteral Feeding System

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Nutrition End Connector

- Introduced in 2012
- Adopted across the market by enteral industry
- Prevents inadvertent use of IV tubing as an administration set.
- Will be an ISO 18250 Standard for reservoir connectors

FROM

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

**CURRENT**

**Male** Stepped or “Christmas Tree” Connector from Administration Set

**Female** Feeding Tube Port

**NEW**

**Female** ENFit Connector from Administration Set

**Male** ENFit Connector for Feeding Tube

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ENFit Transition Connector

**Current**

Female ENFit Connector from Administration Set

**Temporary Transition**

Transition Connector

**NEW**

Female Feeding Tube Port

[Stayconnected2015.org](http://Stayconnected2015.org)
US Enteral Patient Access Estimated Launch Timelines

ENFit

- Transition Set Launch
- New Syringe Launch
- Launch ISO Tubes
- Transition Set Rampdown

Timeline:
- Oct ’14
- Dec ’14
- Jan ’15
- Feb ’15
- Mar ’15
- Apr ’15
- May ’15
- June ’14
- July ’15
- Sep ’15
- Jan ’16

Events:
- Approved DIS
- FDIS Submitted
- FDA Recognized ANSI/AAMI Standard
- FDIS Approved
- PUBLISHED ISO Standard

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ENFit Transition Connector

• Allows fitment to current feeding ports until new enteral feeding tubes are available.

• Available Q1 2015 in all administration set.

• Used during year of transition.
Enteral Syringes with ENFit Connectors

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

• Will now require this Enteral Specific syringe with ENFit female connector

• Oral, Luer or cath-tip syringe will no longer fit

• Available Q2 - 2015

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ENFit Feeding Tube

- Reversed orientation from female to male port
- Locking & forcing function features
- All enteral and multi-purpose ports must have ENFit connector
- Available Q3 2015

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Stay Connected Communications Initiative

• Global communications program to introduce new standard connectors
• Four phases—Aware, Prepare, Adopt & Measure to facilitate the transition
• Improve patient safety by reducing the risk of medical device tubing misconnections
• Starting in 2014 with enteral devices
• Eventually introduce new standard connectors for specific delivery systems including neuraxial, limb cuff inflation, and respiratory applications

• www.StayConnected2015.org
Preparing for Change

• **Concerns: Distribution, Adoption, Conversion and Compatibility**
  • Ordering and Stocking of Supplies
  • Supplier Part Numbers
  • Adopt the new devices
    • Patient transfers between facilities or healthcare systems
    • Prepare and avoid potential delays in healthcare services
    • New staff orientation and education to devices
PREPARE Transition Checklists

Get ready for the new ENFit connector
Transitions Checklist for Home Care Providers

A new global design standard for medical device tubing connectors is on its way. Starting with enteral feeding and the new ENFit connector, distinct standards for clinical applications 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 is a global transition, starting in the US, Canada, and Puerto Rico, with the goal of completion in these markets by 2016. Every organization has a different process for implementing change, but all require a well-informed, properly prepared team.

Follow the STEPS below to aid in a smooth transition:

**S** Supplier communication
- Learn how the new connectors will work and differ from current system
- Familiarize yourself with all the product-specific changes
- Understand anticipated timing of the transition

**T** Training
- Select a care team to train staff and patients/caregivers
- Identify a timeline and vehicles for communication
- Communicate importance of connector changes to enhance patient safety
- Distribute patient/caregiver checklist
- Explain how new feeding sets will change and demonstrate how they will connect
- Encourage patients/caregivers to use up entire inventory of current products first, then transition to new ENFit transition sets
- Reinforce locking feature and safety benefits of the new ENFit connector

**E** Education
- Plan educational opportunities for all patients/caregivers on:
  - Administering enteral formula
  - Flushing the tube and checking residuals as appropriate
  - Administering medications
  - Providing additional hydration
- Visit StayConnected2014.org for connector transition information
- Encourage patients to ask questions. Direct any product-specific questions or complaints to the manufacturer/supplier
- Direct procedural questions to a multidisciplinary transition team

**P** Process
- Organizations of all sizes should strongly consider assembling a multidisciplinary transition team to evaluate current procedures and protocols
- Transition teams should fine-tune procedures and protocols to include the new ENFit connectors

**S** Supply management
- Reduce excess inventory levels of enteral feeding devices with current connectors (this includes feeding/administration sets, syringes, and feeding tubes)
- Allow products with the new ENFit Transition Connectors and final ENFit feeding tubes to flow through according to customer demand
- Avoid overstocking any enteral feeding products

![Diagram with ENFit connector changes](image-url)

Enteral System Connector Changes

The new design standard impacts the entire enteral feeding system.

- **Patient-Access End**
  - New ENFit female connector
  - ENFit Transition Connector

- **Syringe (Current)**
  - Syringes to administer medicine, flush, hydrate, or bolus feed
  - New ENFit female connector

- **Feeding Tube (Current)**
  - Transition set (temporary)
  - Allows fitment to current feeding port until new ENFit enteral feeding tubes are available

- **Feeding Tube (Final)**
  - Changing from male—stepped or Christmas tree connector—to the new ENFit female connector
  - Feeding tube part for the administration set will change from female to male.

For more information and to sign up for updates, visit StayConnected2014.org
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- NeoMed
- Nestle
- Nutricia
- Smith’s Medical
- Vygon
- Xeridiem
- VR Medical/Kentec
Stay Connected Driven by Industry, Supply Chain, Clinician & Patient Partnership

Developed by GEDSA in partnership with experts from leading organizations
New Joint Commission Sentinel Event Alert

• Issued August 20, 2014
• Also includes text and list of particular standards in all care areas where this applies
• http://www.jointcommission.org/sentinel_event.aspx
Recommendations for Health Care Facilities

• Plan, communicate and train
  • Familiarize your organization with new standard connectors
  • Work with manufacturers and suppliers to train staff on the use of the new connector design
  • Develop an interdisciplinary team to help transition to new standards

• Avoid modifying or adapting the device or it’s connector outside of it’s intended application since this may defeat the safety system

• Report adverse events to FDA
  • Before, during, and after the transition occurs in your facility
  • Helps FDA assess benefit of change
  • Helps FDA monitor success of the transition in the healthcare setting

Stayconnected2015.org
Leverage Resources at stayconnected2015.org

- Transition checklists
  - Clinicians
  - Administration
  - Supply Chain
  - Pharmacy
  - Homecare Provider
  - Patient
- Brochures & In-Service presentations
- References & Recent Articles
- YouTube Videos
- FAQs
Thank you for your time today!

EMAIL

tom@gedsa.org

Important Links:

www.StayConnected2015.org

AAMI

FDA- (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

Joint Commission

Nutritioncare.org