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New standards for medical tubing connectors: Are you ready?

August 20, 2014

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• Advisor Live archive page at www.PremierInc.com/AdvisorLive
• Premier Safety Institute www.premierinc.com/tubingmisconnections
Faculty

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What is a tubing misconnection?

A serious adverse patient safety event resulting in harm and possible death

An inadvertent connection of tubing from the medical device for one delivery system to a system that serves a completely different function

- Formula delivered via IV instead of feeding tube
- IV fluids connected to breathing circuit
- Blood pressure tubing connected to IV line

Also known as

- Luer misconnections
- Small bore misconnections
- Wrong route error

Photo courtesy of FDA
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
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
“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
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
  - USP
  - ISMP
- Many incidents / law suits settled – not reported
- First case report published in the literature, 1972
  - Case report analysis by Simmons, 2011 included 116 cases
- Low incidence, but results in *life-altering injury or death*
Practice guidance, alerts have not solved this 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**
  » *Making Healthcare Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*

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

- **ISMP - Institute for Safe Medication Practices**
  » Several medication safety alerts, self-assessment tool
Tubing misconnections: 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
Scott Colburn, RN, MS
Director of standards program,
U.S. FDA, Centers for Devices and Radiologic Health

Pamela D Scott,
Senior Science Health Advisor
U.S. FDA, Center for Devices and Radiological Health
Why is this important?

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.

In the US The Joint Commission has put out information (amongst others);

- 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.
The disaster revealed serious shortcomings in the handling of large-scale medical emergencies… More confusion was added-to by the American military using different standards for intravenous catheters from German paramedics before a single standard was codified in 1995.
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.
ISO 80369-1 General Requirements

- 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 in standard-
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 2010-05-24 (M)
PG7: Luer Lock-r2 (F), Luer Lock-r2 (M), Needless-r2 (F)
Overlapping MAX/MIN ID and OD:

Possible Misconnection (RED)

Within RESIDUAL INTERFERANCE or RESIDUAL GAP

Questionable (YELLOW) Or UNDEFINED

No overlap or intended to connect

Non-connectable (GREEN Or Designed to Connect)
Based on Initial Proposals
When organized other bands would be available for other therapeutic areas

Current Luer would occupy this band

New Proposal
# Screening Tool

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**Note:** The table above represents a summary of screening tools for various conditions. Each cell may contain specific details or criteria for assessment.
2006 MedSun Survey

- 16% of surveyed facilities experienced an enteral misconnection incident

Continued MDR Reports

- Blood pressure tubing connected to the patient Luer lock IV line in the PACU after carpal tunnel surgery. Resulted in death of the patient.
- The tubing for a non-invasive lower arterial vascular study was plugged into an IV line port instead of the cuff tubing. The slide clamp on the IV tubing prevented a major air embolism.
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](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

- Recognition of ISO 80369-1
FDA’s Current and Ongoing Efforts

July 2010 Letter to:
- Enteral Feeding Tube Manufacturers
- Healthcare Professionals
- Hospital Purchasing Departments

Draft Guidance document for devices that contain small-bore connectors designed for enteral applications
- For Industry and FDA Review Staff

We are working with healthcare organizations to promote education of healthcare providers, users, and patients about this effort
FDA is considering the best regulatory tools for implementation of these standards, such as:

• Standards recognition

• Special controls, such as guidance documents, to provide a reasonable assurance of the safety and effectiveness of a device

FDA will work with manufacturers to implement a regulatory pathway that will enable manufacturers to transition their devices to the new connector designs.
FDA is considering the best regulatory tools for implementation of these standards, such as:

- Standards recognition

- Special controls, such as guidance documents, to provide a reasonable assurance of the safety and effectiveness of a device

FDA will work with manufacturers to implement a regulatory pathway that will enable manufacturers to transition their devices to the new connector designs.
Recommendations for Health Care Professionals

The key to a successful transition to new connectors in the health care setting will be planning, communication and training

• Work with manufacturers and suppliers to train staff on the use of the new connector designs
• Ensure staff understand the proper use to transition connectors, if available
• Communicate transition to all affected departments within the facility

Avoid modifying or adapting the device or it’s connector outside of it’s intended application since this may defeat the safety system
Recommendations for Health Care Professionals

Health care facilities can prepare by purchasing and using devices with the new connectors once they become available on the market.

Health care facilities can prepare by developing a plan for transitioning devices with old connector designs from inventory and replacing them with devices with the new ISO connectors.

Report adverse events to FDA

- Before, during, and after the transition occurs in your facility.
- Will aid FDA in assessing benefit of change.
- Will help FDA monitor success of the transition in the healthcare setting.
How to Report an Adverse Event to 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.
Types of adverse event information needed

Clear and detailed description of event
- Include what devices should connect and what shouldn’t have been able to be connected
- Identify the event as a misconnection or potential misconnection

All devices relevant to the event

All known device identifiers (e.g., brand name, model number) for relevant devices involved in event

Patient age, gender, and medical outcome

Location of misconnection event (e.g. hospital, home, etc.)

Type of adverse event, if applicable, resulting from misconnection
- Report “near misses” even if no patient injury occurred
Contact information:

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Thomas J. Hancock, MBA,
Executive director,
GEDSA - Global Enteral Device Supplier Association
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 mgmt
- Train Clinicians and Materials/Inventory Management Staff

**ADOPT**
- Introduce new connectors into work stream to reduce tubing set misconnections and improve patient safety
- Transition & Integration into medical practice

**MEASURE**
- Measure teams ability to adopt changes and reassess how to improve the process for next phase
- Post execution monitoring, metrics, feedback processes
3 Phases of Delivery System Launches

**PHASE I - Enteral**

- **Q1'14** to **Q4'14**
- **Q4'14** to **Q2'15**
- **Q2'15** to **Q3'15**

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<td>Product Launch &amp; Implementation</td>
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**PHASE II - Neuraxial**

- **Q3'15** to **Q4'15**
- **Q1'16** to **Q2'16**

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**PHASE III – Therapeutic Family TBD**

- **Q3'15**
- **Q4'15**
- **Q1'16** to **Q2'16**
- **Q3'16**
- **Q4'16**
- **Q1'17**
- **Q2'17**

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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
The Challenge...Connecting a System Designed Not to Connect

**CURRENT**

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

**Female** Feeding Tube Port

**NEW**

**ENFit**

**Female** ENFit Connector from Administration Set

**Male** ENFit Connector for Feeding Tube
ENFit Transition Connector

Current

Female ENFit Connector from Administration Set

Temporary Transition

Transition Connector

Female Feeding Tube Port

NEW
US Enteral Patient Access
Estimated Launch Timelines

**ENFit Connector Transition**

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

**Timeline:**
- Jun '14
- Aug '14
- Oct '14
- Nov '14
- Dec '14
- Jan '15
- Feb '15
- Mar '15
- Apr '15
- May '15
- July '15
- Sep '15
- Jan '16

- FDA Recognized ANSI/AAMI Standard
- FDIS Submitted
- FDIS Approved
- PUBLISHED Jan'15

CA Deadline
ENFit Transition Connector

- Allows fitment to current feeding ports until new enteral feeding tubes are available.
- Available Q4 2014 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 Q1 - 2015
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 Q2 2015
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.StayConnected2014.org
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Stay Connected Driven by Industry, Supply Chain, Clinician & Patient Partnership

Developed by Global Enteral Device Supplier Association (GEDSA) in partnership with experts from leading industry organizations.
Debby Kasper, RD, LD
Director, clinical nutrition, Premier, Inc.
Now what?
Designate a Champion

- Coordination
- Communication
  - Facility
  - Supplier(s)
Who is going to be impacted?

- Nurses
- Medical Staff
- Pharmacy
- RD
- Unit Secretaries
- IT
- Materials Management
- Education Department
- Social Workers
- Risk Managers or Patient Safety Officers
- Units (ED, OR, ICU, GI Lab)
- Home Health Agencies
**Discovery**

- **Inservice**
  - Tools on GEDSA website

- **Identify your current suppliers**

- **Outline your processes and protocols**
  - How do feeding tubes get ordered?
  - How are they stocked?
  - Are they on order sets or standing orders?
  - Are they listed in EMR’s?
  - How is medication for use thorough tubes ordered/delivered?

- **Patient education material**

- **Who needs to know what and when?**
Consolidate Inventory

- Includes feeding tubes, connectors, and enteral specific syringes
- Check units
- Storage areas
- Drawers
- Closets
Develop a Plan

- Identify Super Users

- Education
  - Who, what, where, when, how

- Communication
  - Orders
    - Electronic
    - Paper
  - Education materials
  - Other organizations/agencies involved

- Inventory
  - Amount
  - Physical space
  - Labelling
Evaluation

How is the plan working?

Glitches in the system
Checklists on GEDSA

- Facilities
- Nurse/Clinicians
- Supply Chain
- Pharmacies
- Home Health
- Patients / Caregivers
Mike Cohen, RPh, MS, ScD,
President, Institute for Safe Medication Practices
Horsham, PA 19044
Unit doses of liquid medications can no longer be prepared or administered using an oral syringe when patient has feeding tube with ENFit connectors.

We are strongly recommending that patient specific doses be prepared:
- Meds should be properly labeled and bar-coded for bedside scanning.
- Good communication methods between pharmacy and patient care areas is critical (which patients have feeding tubes vs. needing oral liquids for other reasons)?

Bottle adapters to fill liquid ENFit syringes:
- Screw on, snap in, and Christmas Tree-type adapters are available for use with oral syringes, but, so far, not for the new ENFit syringes.
- Can transition set add-on be used for liquid filling?
Caps for syringes so they can be easily transported

Other means of dispensing liquids for feeding tubes
  • Pharmacy dispensing liquid unit dose cups for nurses to prepare at bedside
  • Unintended consequences
  • Possibility of jury-rigging

Organizations should determine an alternative process for safely dispensing patient-specific doses in labeled, bar-coded, unit-dose cups or vials

Reinforce purpose of change. Continue to make staff aware of the transition to new enteral connectors. Remind them that the initiative will enhance patient safety by reducing the risk of harmful tubing/catheter misconnections (e.g., enteral feeding injected IV).
Assign individual or subgroup of implementation team to stay updated and share transition updates with the full team. Maintain regular contact

- **Stay Connected.** The Global Enteral Device Supplier Association (GEDSA), the coalition formed to help introduce new medical device connectors, maintains a Stay Connected website (www.stayconnected2014.org/) to keep healthcare providers up-to-date. Email notifications are available when new information has been posted.

- **ISMP.** We will provide regular updates impacting enteral connector transition (e.g., availability of caps, bottle adapters, educational programs) (www.ismp.org).

- **Purchasers/suppliers.** Stay in the loop to receive notifications and other information provided by purchasers and suppliers as the transition moves forward.

http://www.ismp.org/Newsletters/acuteCare/showArticle.aspx?id=86
Resources- Links

- Webinar – Aug 20
  - Slides, audio
- Stay-Connected website
- FAQs: general, enteral
- FDA
- CMS memo
- AAMI
- ISMP
- Joint Commission
- ASPEN
QUESTIONS?

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Thank you for joining us

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