Small-bore Connectors –
New Standards and Designs

May 31, 2014  3:15 – 4:30 pm
Speakers & Panelists

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Director of the Standards Program at the FDA’s Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration (FDA)

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Executive Director California Hospital Patient safety Organization (CHPSO)

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Director Clinical Technology & Biomedical Engineering Information Technology/Information Services Stanford University Medical Center
Learning Objectives

1. Explain why new small-bore connector design standards are needed
2. Describe features of the new small-bore connector standards and their safety implications
3. Outline the timeline for new connector design implementation and transition using enteral connector as an example
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.

Luer Connector:
• Classic type of a small-bore connector
• Universal connector
• Used commonly in the healthcare setting
Small-bore Misconnection

Definition:
An inadvertent connection between one system and an unlike system such as an enteral, blood pressure device, intravascular catheter, peritoneal dialysis catheter, tracheostomy, medical gas tubing, etc.
Misconnection: 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.

Misconnections- How can this happen?

Obvious

Not so obvious

FDA Medical Device Safety Calendar, 2009
Misconnections: Contributing Factors

• Human Factors
  – Distraction
  – Fatigue
  – Poor Lighting

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

• Product manufacturers are urged to implement “incompatibility by design” features.¹
• Mechanical incompatibility 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 80369-1:2010 General requirements standard

ISO 80369-1, Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements

80369-2 Breathing systems and driving gases Applications (respiratory)
80369-3 Enteral applications
80369-4 Urethral and urinary applications (planned but not started)
80369-5 Limb cuff inflation applications (NIBP HP)
80369-6 Neuraxial Applications
80369-7 Intravascular or hypodermic applications (6% (Luer) taper)

Requirements:
- Not connectable with others in series
- Rigid or semi-rigid
- Misconnection test with other devices

Note: Reservoir connectors are covered under a separate series of standards (ISO 18250 series) still under development. Enteral connector has been introduced as an industry standard in the US, Europe and other markets.
Who is ISO and why them...

- **International Organization of Standardization (ISO)**
  - 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
International standards development

- ISO is a federation of 162 countries (not all countries participate in all standards)
- One country, one vote
- ISO is made up of Technical committees, subcommittees and working groups
- Working groups are made up of experts from industry, users, and government/regulatory bodies
- The small-bore connectors standards are developed in a joint working group under ISO/TC 210, Quality management and corresponding general aspects for medical devices IEC/SC 62D, Electromedical equipment
Standards process… why so long to get there….

• Risk
  – Standard may introduce greater risk
  – Consensus on solution
  – Global adoption

• Adoption
  – Voluntary…need consensus and buy-in

• Validation
  – Simulation of user environment, design, material, manufacturing, processes

• Conversion
  – Manufacturers
  – Market
  – Supply
# 80369 Small-Bore Connectors
## International Standards Development Timeline

<table>
<thead>
<tr>
<th>Standard</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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<tbody>
<tr>
<td>80369-2, Connectors for breathing systems and driving gases applications</td>
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<tr>
<td>80369-3, Connectors for enteral applications*</td>
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<td>80369-5, Connectors for limb cuff inflation applications</td>
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<td>80369-6, Connectors for neuraxial applications</td>
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<td>80369-7, Connectors with 6% (Luer) taper for intravascular or hypodermic applications</td>
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<td>80369-20, Common test methods</td>
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### Key
- **Submission of DIS text to ISO**
- **DIS (Draft International Standard) balloting**
- **FDIS (Final Draft Intl. Std.) balloting**
- **ISO publication**

*refers to second DIS ballot; first DIS ballot was Disapproved

May 2014
California Law Summary

Health facilities affected; 1250(a): general acute care hospitals; 1250(b): acute psychiatric hospitals; 1250(c): skilled nursing facilities; 1250(f): special hospitals (dentistry or maternity)

1279.7.
(a) A health facility, as defined in subdivision (a), (b), (c), or (f) of Section 1250, shall implement a facility-wide hand hygiene program.

(b) Commencing January 1, 2016, a health facility, as defined in subdivision (a), (b), (c), or (f) of Section 1250, is prohibited from using an epidural connector that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care.

(c) Commencing January 1, 2016, a health facility, as defined in subdivision (a), (b), (c), or (f) of Section 1250, is prohibited from using an intravenous connector or an enteral feeding connector that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care.

(d) The Advanced Medical Technology Association shall, on January 1 of each year until the standards are developed, provide the Legislature with a report on the progress of the International Organization for Standardization in developing new design standards for connectors for intravenous, epidural, or enteral applications.

(e) A health facility that is required to develop a patient safety plan pursuant to Section 1279.6 shall include in the patient safety plan measures to prevent adverse events associated with misconnecting intravenous, enteral feeding, and epidural lines. This subdivision shall become inoperative as to epidural connectors upon the operative date of subdivision (b) and as to intravenous and enteral connectors upon the operative date of subdivision (c).
Enteral Misconnection
Events and Alerts

TIMELINE: Enteral Misconnections

1972: First case report in literature, The Lancet
1979: Call for international enteral feeding apparatus not compatible with IV lines
1980s: Case report suggests incompatible connectors
1990: AAMI standard passed in 1995 with specific guidelines for feeding tubes – not luer lock compatible
2005: AAMI standard released
2006: FDA publication

LEGEND:
Agency Alerts
= Case Report

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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, CNS\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
## Reported Enteral Misconnections and Related Factors


<table>
<thead>
<tr>
<th>Related Factors</th>
<th>Cases</th>
<th>Sentinel Events</th>
<th>% Sentinel Event</th>
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</thead>
<tbody>
<tr>
<td>Use of Syringe Pump and IV Tubing</td>
<td>1</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Use of Ready-to-Hang Enteral Containers/Bags and IV Tubing</td>
<td>3</td>
<td>2</td>
<td>66%</td>
</tr>
<tr>
<td>Enteral Meds Administered IV (Used IV Syringe)</td>
<td>13</td>
<td>3</td>
<td>23%</td>
</tr>
<tr>
<td>Other Solution Intended for Enteral Route given IV</td>
<td>4</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>Enteral Tube Not in Place, Med Given IV</td>
<td>3</td>
<td>1</td>
<td>33%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>24</td>
<td>8</td>
<td>33%</td>
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Future Enteral Feeding System

**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**
ENFit

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

Feeding Bag/Container with Spikeable Tubing Set with Spike

Complete

Est. Q3 2014
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
ENFit Patient-Access Connector Timeline

FROM

TO

US, Canada & PR Transition:

- **Q4 2014**  Administration Sets
- **Q1 2015**  Enteral Syringes
- **Q2 2015**  Feeding Tubes
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
Transition Concerns

Inconsistent Adoption:
• Certain facilities may adopt the new devices before others do
• If a patient with the new device is transferred to a facility with old devices, a transition connector is needed
• If a patient with an old device is transferred to a facility with new devices, a transition connector is needed
• Creates delays in care unless recipient facility already has the connector readily available or a transition connector is supplied for transport
• Availability of a full range of compatible devices as needed for patient care

Recommendation:
• Include assessment of connector types on transfer and on admission to anticipate and resolve connector challenges
Mis-filled syringes or fluid reservoirs

- Remain an issue, currently appears to happen much less frequently than misconnections of properly filled containers
- Nurses still need to be aware of correct route for each medication, and systems (e.g., CPOE) should continue to check for proper route
- The new connectors are a component of “defense in depth” for potentially disastrous events, not a substitute for current defenses
Stay Connected Communications Initiative

- Global communications program to introduce new standard connectors
- An effort to improve patient safety by reducing the risk of medical device tubing misconnections
- Four phases—Aware, Prepare, Adopt & Measure to facilitate the transition
- Starting in 2014 with enteral devices
- Introduce new standard connectors for other delivery systems including neuraxial, and respiratory applications
- www.StayConnected2014.org
Stay Connected Partnership of Industry, Supply Chain, Clinician & Patient

Developed by Global Enteral Device Supplier Association (GEDSA) in partnership with experts from leading industry organizations
Stay Connected

AWARE

What you can do:

• Inform impacted personnel of impending changes across the organizations

• Impacted Personnel - clinicians, administrators, supply chain, health technology management and other support staff.

• Identify a leader to stay informed and communicate updates early and often.
Stay Connected
PREPARE

What you can do:

• Form teams to assess existing systems, processes, and protocols that may need to change
• Focus on areas of highest risk with the most immediate need to convert to the new connectors
• Work with supplier representatives and adopt their product specific transition plan
• Look for education opportunities to train staff
Stay Connected
ADOPT

What you can do:

• Introduce new connectors into work stream to reduce tubing misconnections and improve patient safety.

• Remind organization of long-term benefits vs. short-term hassles of transitioning
Stay Connected - Enteral US, Canada & PR Timeline

Four Phased Approach

- **AWARE**: Now thru Summer 2014
- **PREPARE**: Fall 2014/Winter 2015
- **ADOPT**: Q4 2014 – Q2 2015
- **MEASURE**: 2015
Summary

• Get the Facts  - Access the FAQs
• Become an institutional champion for change
• Go back and form awareness groups including all stakeholders
• Watch for educational offerings
  www.nutritioncare.org/ENtoolkit
• Go to www.StayConnected2014.org
Resources Now

• FAQs, Brochures, Articles, References and Other Resources at:  www.StayConnected2014.org
• EN Safety Campaign: A.S.P.E.N website: www.nutritioncare.org/ENToolkit
• AAMI website:
  http://www.aami.org/hottopics/connectors/index.html
• FDA Website:
  http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
Panel Discussion Format

- Opening Remarks
- Questions & Answers
- Close
Wrap-up

• Thanks to the speakers/panelists
• Thanks for your attention and participation
• Presentation will be available at AAMI University
• Expo Hall is now open and we will be hosting the Grand Opening Reception until 7:00 pm.
• Please drop off your Evaluation Form on your way out.

Thank you again!
Back-up
Health facilities affected

• 1250(a): general acute care hospitals
• 1250(b): acute psychiatric hospitals
• 1250(c): skilled nursing facilities
• 1250(f): special hospitals (dentistry or maternity)
Epidural

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Intravenous, Enteral

Commencing January 1, 2016, a health facility, as defined in subdivision (a), (b), (c), or (f) of Section 1250, is prohibited from using an intravenous connector or an enteral feeding connector that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care.
Updates to the Legislature

The Advanced Medical Technology Association shall, on January 1 of each year until the standards are developed, provide the Legislature with a report on the progress of the International Organization for Standardization in developing new design standards for connectors for intravenous, epidural, or enteral applications.
The Draft International Standard … for IV has been approved and the Draft International Standard for enteral is expected to be approved by early 2014, while the neuraxial (epidural) standard is expected in Q3 2014. Final published standards for enteral and IV are, at the earliest, not expected until June 2014 and neuraxial (epidural) is expected Q1 2015.
Progress to Meet Deadline

A group of manufacturers and interested parties, including the California Hospital Patient Safety Organization, is working closely together to plan and coordinate all of the steps necessary to meet the January 1, 2016 requirement in California. We continue to believe the date is attainable.