

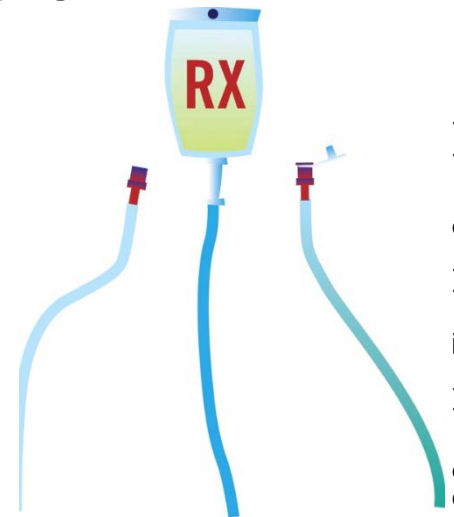
# Webinar

## **New ISO Tubing Connector Standards:**

**A Follow-up to the *Sentinel Event Alert***

**December 3, 2014**

**Hosted by The Joint Commission**



# Featured Presenters



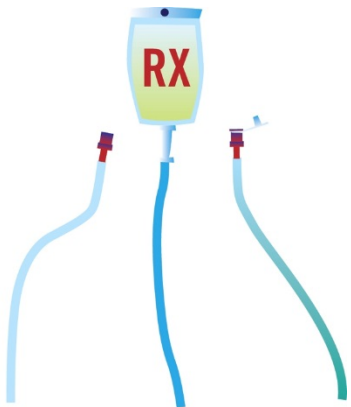
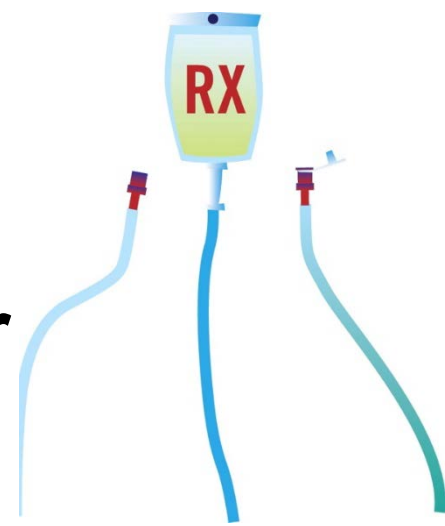
- **Ronald Wyatt, M.D. (The Joint Commission)**
- **Thomas J. Hancock (GEDSA)**
- **Peggi Guenter, Ph.D., R.N., FAAN (A.S.P.E.N)**
- **Mike Cohen, R.Ph., M.S. (ISMP)**
- **Amy Wilson, R.N., M.S.N., CPHQ (Sacred Heart Hospital, Pensacola, Florida)**
- **Sarah Amole, R.N., M.S.N. (Sacred Heart Hospital, Pensacola, Florida)**

# Webinar

## New ISO Tubing Connector Standards:

A Follow-up To The *Sentinel Event Alert*

Ronald Wyatt, M.D.  
The Joint Commission



# GEDSA Stay Connected Enteral Feeding Device Connector Changes...Introducing ENFit

December 2014



# 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

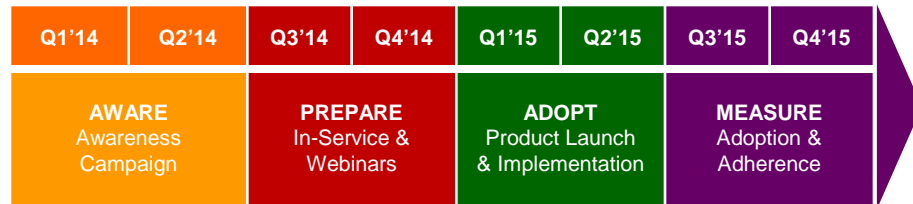
- Transition & Integration into medical practice
- Measure teams ability to adopt changes and reassess how to improve the process for next phase

## MEASURE

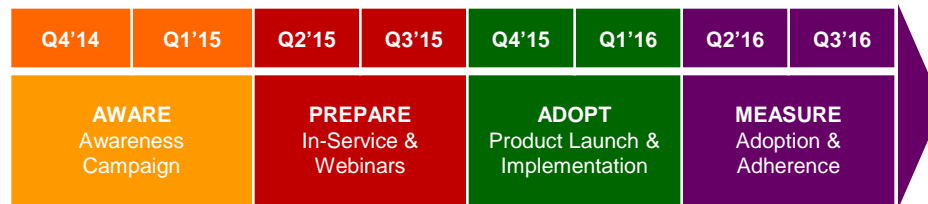
- Post execution monitoring, metrics, feedback processes

# 3 Phases of Delivery System Launches

## PHASE I - Enteral



## PHASE II - Neuraxial



## PHASE III – Therapeutic Family TBD

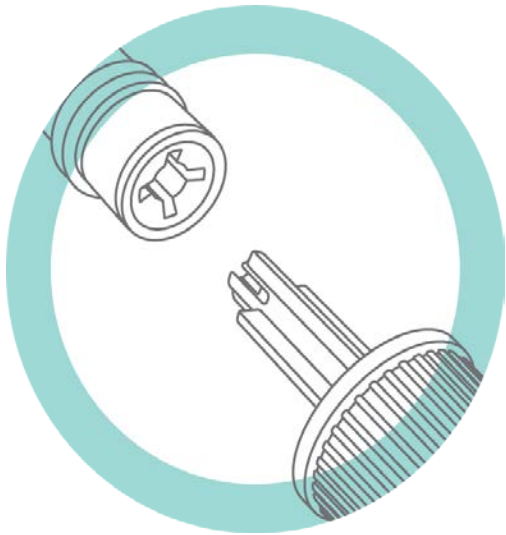


# Nutrition End Connector

**FROM**



**TO**

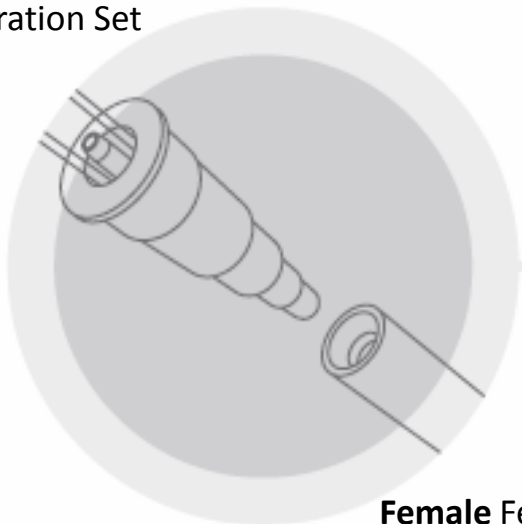


- Introduced in 2012
- Adopted across the market by enteral industry
- Prevents inadvertent use of IV tubing as an administration set.
- Will be an ISO 18250 Standard for reservoir connectors

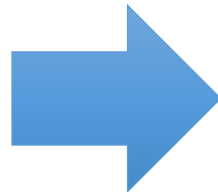
# The Challenge...Connecting a System Designed Not to Connect

## CURRENT

Male Stepped or  
“Christmas Tree”  
Connector from  
Administration Set



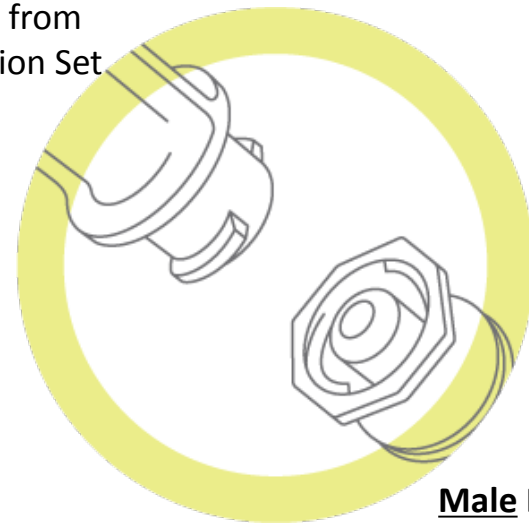
Female Feeding  
Tube Port



## NEW

# ENFit

Female ENFit  
Connector from  
Administration Set



Male ENFit  
Connector for  
Feeding Tube



# ENFit Transition Connector

**Current**

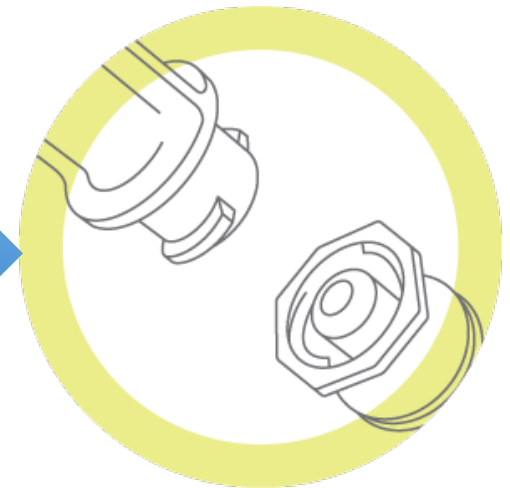
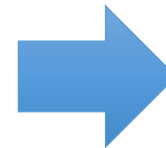
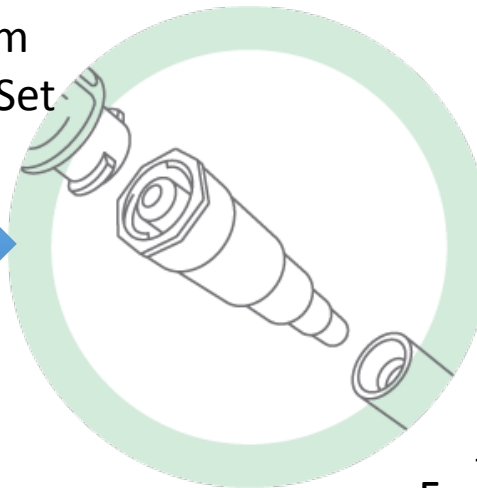
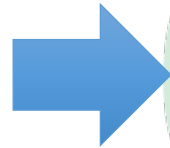
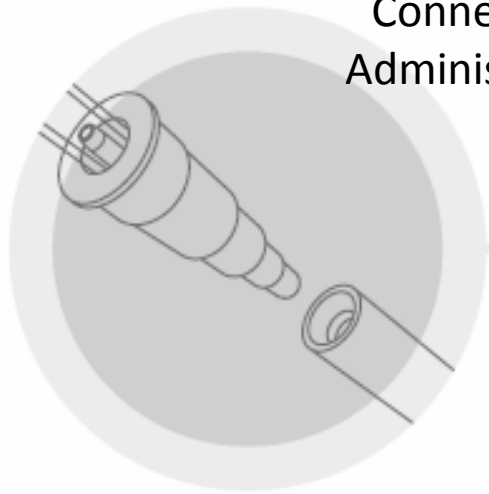
**Temporary Transition**

**NEW**

**Female ENFit**  
Connector from  
Administration Set

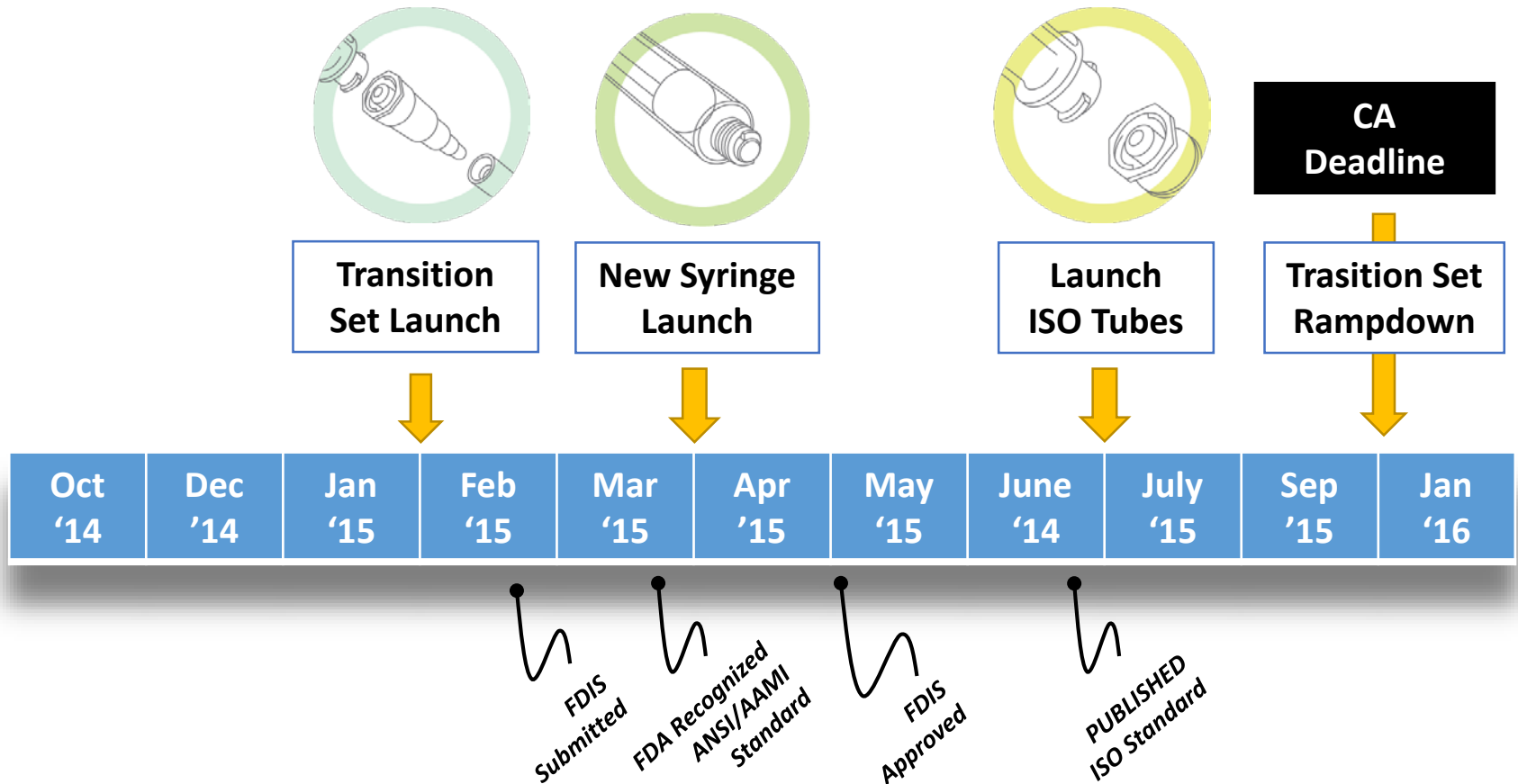
Transition  
Connector

**Female**  
Feeding Tube  
Port

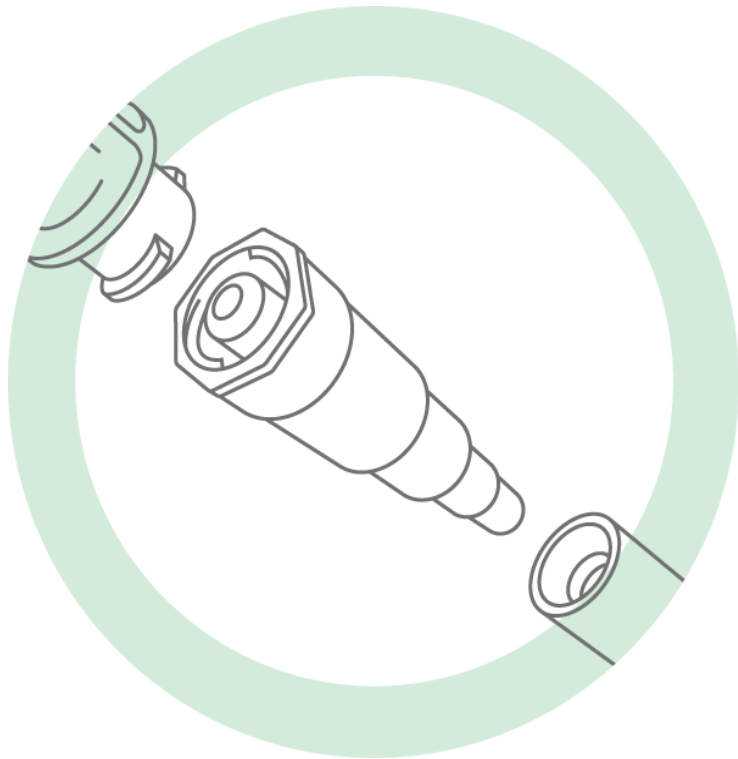


# US Enteral Patient Access Estimated Launch Timelines

## ENFit



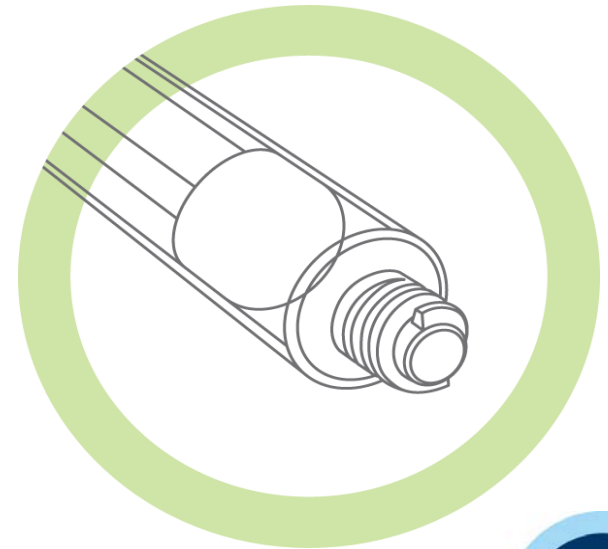
# ENFit Transition Connector



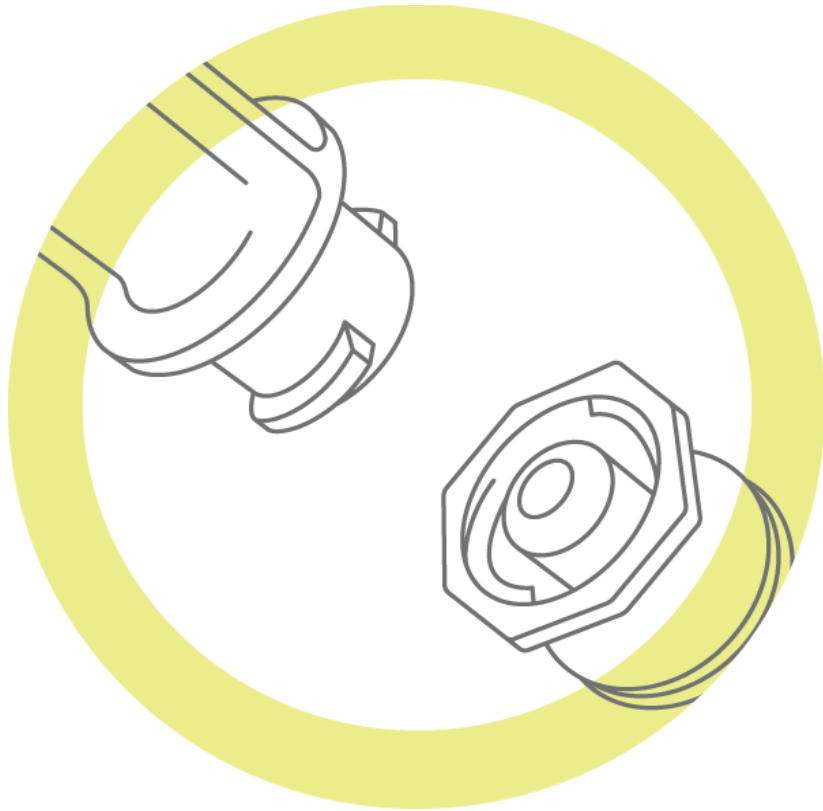
- Allows fitment to current feeding ports until new enteral feeding tubes are available.
- Available Q1 2015 in all administration set.
- Used during year of transition.

# 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



# 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

# 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

# Recommendations

- Begin familiarizing your organization with the new standards
- Develop an interdisciplinary team and begin discussions about new standards
- Utilize resources available to help prepare for change
  - Transition checklist
  - 2013 Healthcare Supply Chain Expo Panel Discussion
  - Raising Awareness Webinar by Peggi Guenter of ASPEN
  - FAQs

# 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](http://www.StayConnected2015.org)



# PREPARE Checklists

## Get ready for the new ENFit connector

### Transition 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.

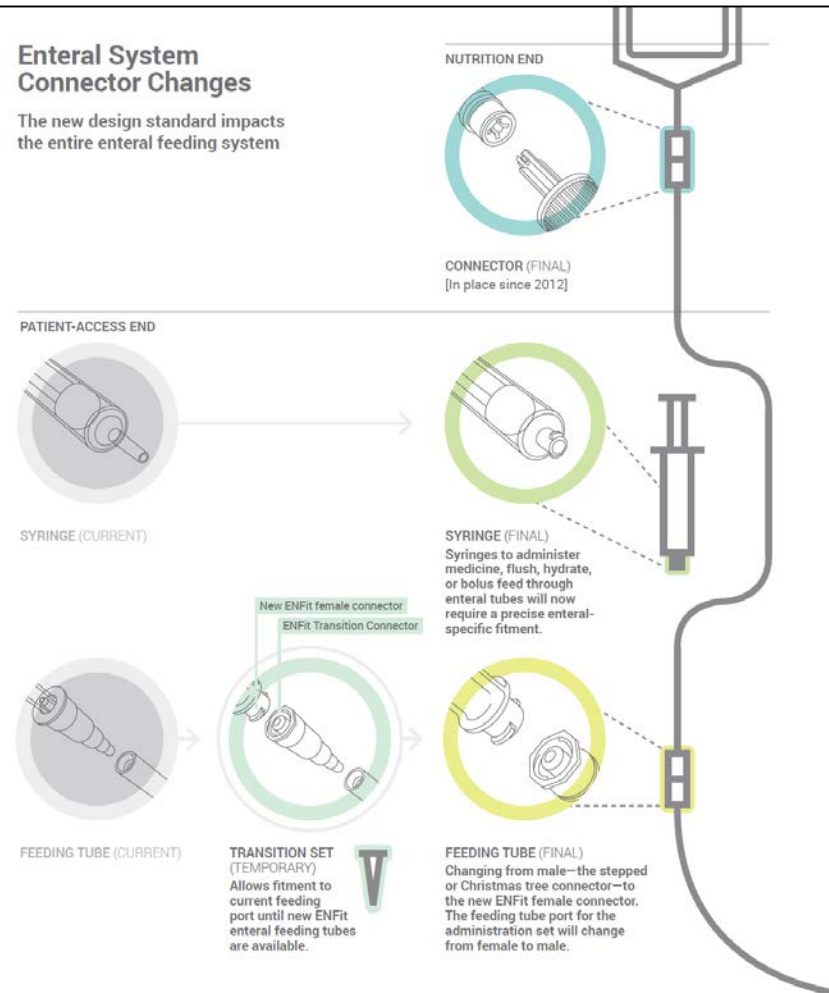
#### Follow the STEPS below to aid in a smooth transition:

<b>S</b>	<b>Supplier communication</b>	<ul style="list-style-type: none"> <li>Learn how the new connectors will work and differ from current system</li> <li>Familiarize yourself with all the product-specific changes</li> <li>Understand anticipated timing of the transition</li> </ul>
<b>T</b>	<b>Training</b>	<ul style="list-style-type: none"> <li>Select a care team to train staff and patients/caregivers</li> <li>Identify a timeline and vehicles for communication</li> <li>Communicate importance of connector changes to enhance patient safety</li> <li>Distribute patient/caregiver checklist</li> <li>Explain how new feeding sets will change and demonstrate how they will connect</li> <li>Encourage patients/caregivers to use up entire inventory of current products first, then transition to new ENFit transition sets</li> <li>Reinforce locking feature and safety benefits of the new ENFit connector</li> </ul>
<b>E</b>	<b>Education</b>	<ul style="list-style-type: none"> <li>Plan educational opportunities for all patients/caregivers on:                             <ul style="list-style-type: none"> <li>Administering enteral formula</li> <li>Flushing the tube and checking residuals as appropriate</li> <li>Administering medications</li> <li>Providing additional hydration</li> </ul> </li> <li>Visit <a href="http://StayConnected2014.org">StayConnected2014.org</a> for connector transition information</li> <li>Encourage patients to ask questions. Direct any product-specific questions or complaints to the manufacturer/supplier</li> <li>Direct procedural questions to a multidisciplinary transition team</li> </ul>
<b>P</b>	<b>Process</b>	<ul style="list-style-type: none"> <li>Organizations of all sizes should strongly consider assembling a multidisciplinary transition team to evaluate current procedures and protocols</li> <li>Transition teams should fine-tune procedures and protocols to include the new ENFit connectors</li> </ul>
<b>S</b>	<b>Supply management</b>	<ul style="list-style-type: none"> <li>Reduce excess inventory levels of enteral feeding devices with current connectors (this includes feeding/administration sets, syringes, and feeding tubes)</li> <li>Allow products with the new ENFit Transition Connectors and final ENFit feeding tubes to flow through according to customer demand</li> <li>Avoid overstocking any enteral feeding products</li> </ul>



## Enteral System Connector Changes

The new design standard impacts the entire enteral feeding system



A.S.P.E.N. [www.nutritioncare.org](http://www.nutritioncare.org)

NHIA [www.nhia.org](http://www.nhia.org)

National Association for Home Care & Hospice [www.nahc.org](http://www.nahc.org)

For more information and to sign up for email updates, visit [StayConnected2014.org](http://StayConnected2014.org).

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# GEDSA Members

## 2014/2015 Members

- Abbott
- AbbVie
- A. Hopf
- Alcor Scientific
- Amsino
- Baxter
- B Braun
- BD
- Boston Scientific
- Cair Lgl
- Cedec/Entek
- Cook Medical
- Corpak
- Covidien
- Dale Medical
- Degania
- Enteral UK
- Fresenius Kabi
- Kimberly Clark
- Medela
- Medicina
- Medline
- Moog
- NeoMed
- Nestle
- Nutricia
- Smith's Medical
- Vygon
- Xeridien
- VR Medical

## Evaluating

- AMT
- Bard
- ConMed
- Footprint Medical
- Hospira
- JMS
- NeoChild
- Philip's
- Pajunk
- Teleflex
- Utah Medical
- Value Plastics (Nordson Med)

# 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



# ***Getting Prepared: New Enteral Connectors***

Peggi Guenter, PhD, RN, FAAN

Senior Director for Clinical Practice, Quality, and Advocacy

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)

Silver Spring, MD

# What is a Small-bore Connector (SBC)?

A small-bore connector is a connector with

- an 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.**







**? Central Venous Catheter**

**? Epidural Catheter**

**? Gastrostomy Tube**

**? Arterial Catheter**

2/7/00

# Enteral Misconnection

Definition: 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

Guenter et al. *The Joint Commission Journal on Quality and Patient Safety* May 2008;34:285-292.

# Impact of Misconnections

A 24-year-old woman was 35 weeks pregnant 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.

Safety May 2008;34:285-292

Guenther et al. The Joint Commission Journal on Quality and Patient

Following a routine carpal tunnel surgical procedure, a PACU nurse hooked the BP monitor to the patients IV which caused an air embolus and killed the patient. The patients' daughter was a PACU nurse at a different facility.

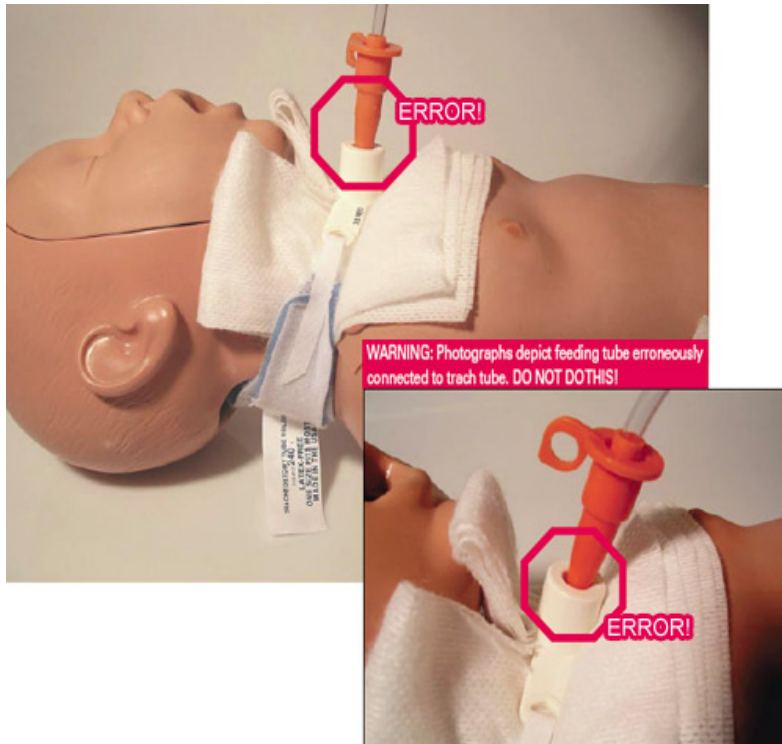


# Misconnections: Two Sets of Victims

In all of these misconnections reports, there are two sets of victims, the patient and family, and the clinician involved. Clinicians never mean to make these mistakes, but they do- because they can.

# Enteral Misconnection- How Can this Happen?

Obvious



Not so obvious



FDA Medical Device Safety Calendar, 2009

# Enteral Misconnections: Contributing Factors

## Human Factors

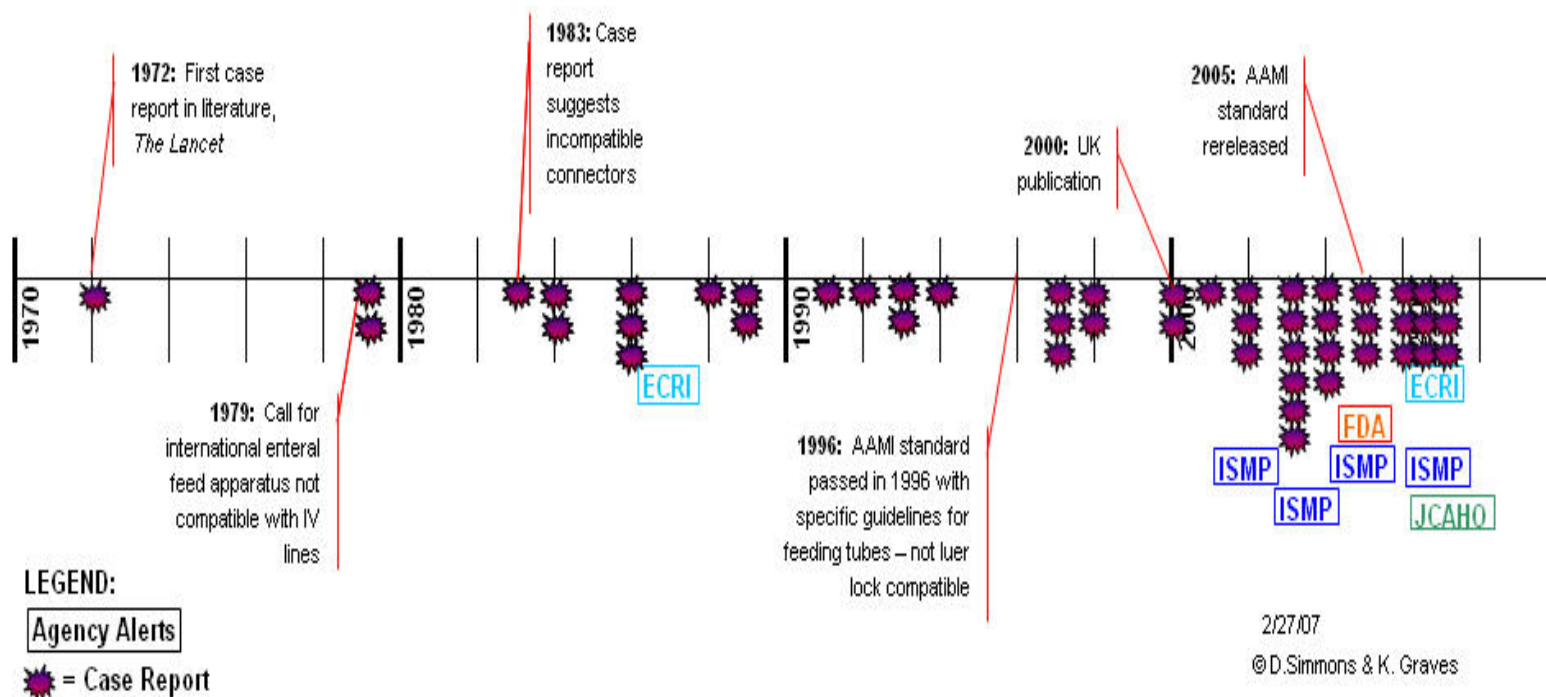
- Healthcare clinician fatigue
- Distraction
- Lighting

## Physical and Design Factors

- Compatible tubing between unlike systems
- Luer connectors
- Use of IV syringes for oral meds
- Universal Spike for bags

# Enteral Misconnection Events and Alerts

## TIMELINE: Enteral Misconnections



# Enteral Misconnections: Published Cases

Invited Review

## Tubing Misconnections: Normalization of Deviance

Debora Simmons, RN, MSN, CCRN, CCNS<sup>1,2</sup>;  
Lene Symes, RN, PhD<sup>1</sup>; Peggi Guenter, RN, PhD, CNSN<sup>3</sup>;  
and Krisanne Graves, RN, MSN, CPHQ<sup>1</sup>

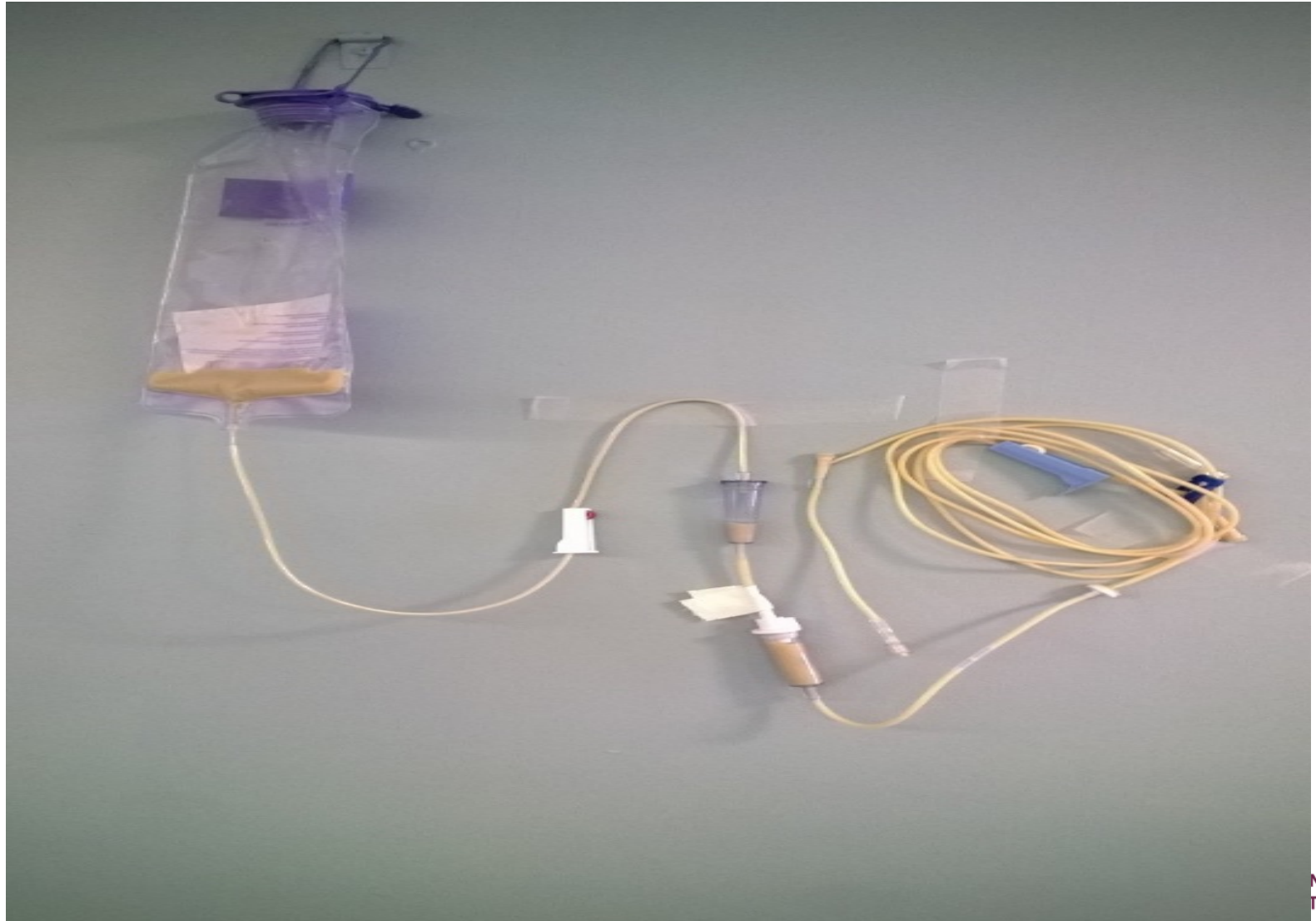
*Financial disclosure: none declared.*

116 published cases as of 2011

Like most errors, highly under-reported

Nutrition in Clinical Practice  
Volume 26 Number 3  
June 2011 286-293  
© 2011 American Society for  
Parenteral and Enteral Nutrition  
10.1177/0884533611406134  
<http://ncp.sagepub.com>  
hosted at  
<http://online.sagepub.com>

# Recent Event

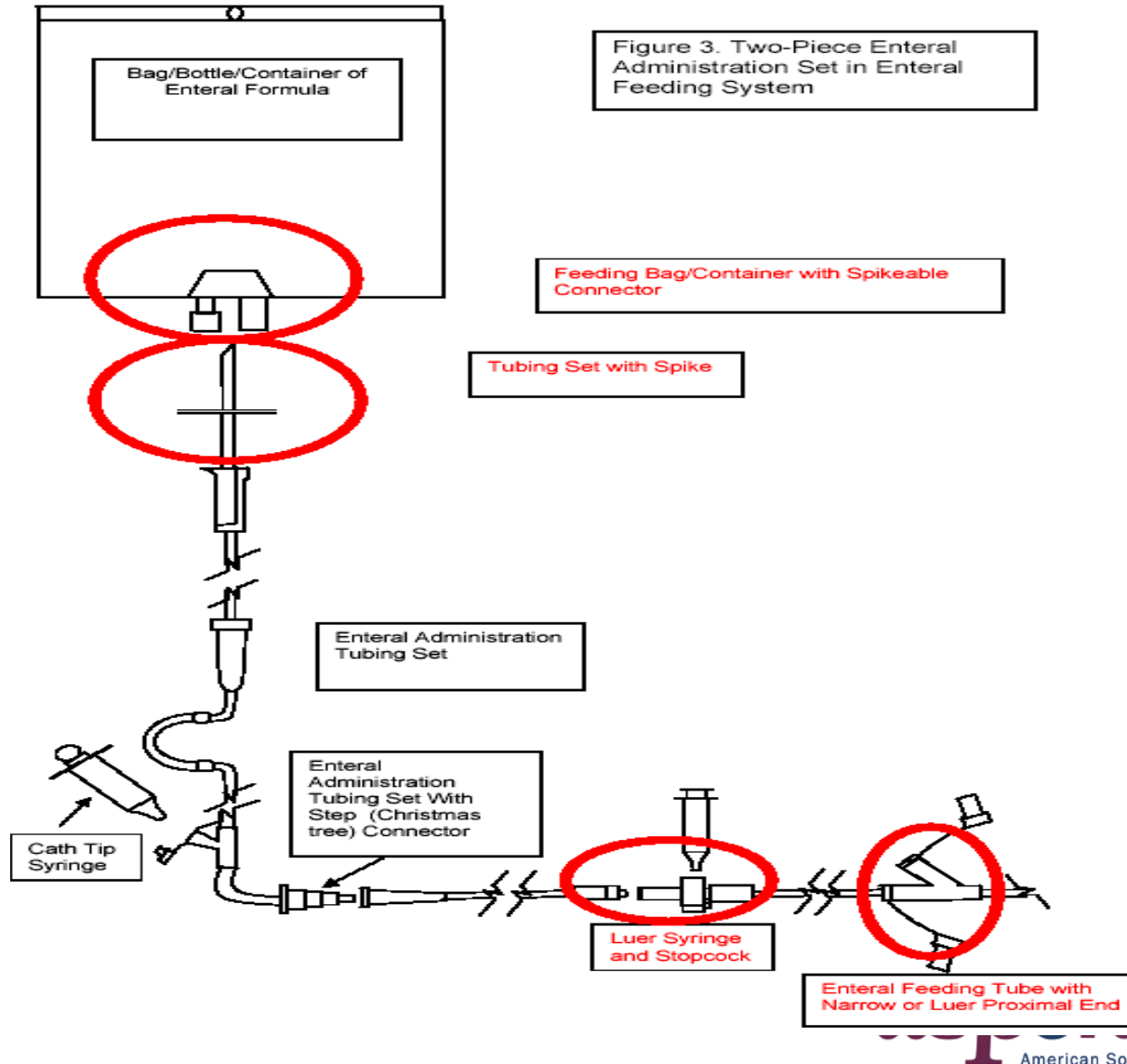


# Reported Enteral Misconnections and Related Factors (Jan. 2000–Dec. 2006 USP data)

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

Guenter et al. *The Joint Commission Journal on Quality and Patient Safety* (2008).

# Enteral Misconnections: Points of Concern





# Enteral Misconnections: 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

# Enteral Nutrition Connector Call for Design Changes

- Product manufacturers are urged to implement “incompatibility by design” features. <sup>1</sup>
- “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.

The Joint Commission Sentinel Event Alert.  
Tubing Misconnections—A Persistent and  
Potentially Deadly Occurrence. March 27, 2006.

# Process Issues

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Mike Cohen  
Institute for Safe Medication Practices

# Process Issues

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- Once new connectors are in place, unit doses of liquid medications for patients with feeding tubes can no longer be prepared or administered using an oral syringe
- 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)?
  - Prescribers should include “via feeding tube” in orders

# Process Issues

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- Bottle adapters to fill liquid ENFit syringes
  - Screw on, snap in, and Christmas Tree-type adapters are available for use with oral syringes. A new adapter for ENFit syringes will also be available.
- Caps for syringes are also going to be available so the new ENFit syringes can be easily transported
- Other means of dispensing liquids for feeding tubes
  - If pharmacy does dispense liquid unit dose cups for nurses, the new syringes can be used to prepare at bedside – but not recommended, won't be labeled and won't have a bar code. Cannot easily rely on bottles of liquids.

# Unresolved Process Dilemmas

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- Unintended consequences - Possibility of jury-rigging
- Can ENFit syringe be used for all unit dose liquids?
- What else will syringes be needed for?
  - Flushing
  - Supplemental hydration
  - Bolus feeding
- Reinforce purpose of change. Continue to make staff aware of the transition to new enteral connectors. Initiative will enhance patient safety by reducing the risk of harmful tubing/catheter misconnections

# Stay Updated

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- 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.stayconnected2015.org/](http://www.stayconnected2015.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](http://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>



# Sacred Heart Hospital Pensacola



**Amy D. Wilson, RN, MSN, CPHQ**  
**Chief Operating Officer, Chief Nursing Officer**  
**Sarah Amole, RN, MSN**  
**Patient Care Manager - Oncology**



# Background

- ❖ Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections can be “rigged” (constructed) using adapters, tubing or catheters.
- ❖ New ISO (International Organization for Standardization) tubing connector standards are being developed for manufacturers.
- ❖ Involves phased implementation of redesigned tubing connectors for:
  - Intravascular or hypodermic applications (luer connectors will be maintained)
  - Limb cuff inflation applications
  - **Enteral applications**
- ❖ The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) has already been adopted and it is anticipated that the new connectors will begin to reach the market as early as the 4<sup>th</sup> quarter 2014.
- ❖ **Enteral Connectors will be introduced first.**

## **Assessment of Current State / Risk Mitigation**

- ❖ Conduct a risk assessment of all tubing connections (Connections Portfolio – Tubing Misconnections Self Assessment for Health Care Facilities, ISMP and Baxter)
- ❖ Implement best practice measures to mitigate the risk of inadvertent tubing misconnections
- ❖ Educate staff about the risk of inadvertent tubing misconnections
- ❖ Ensure a culture of safety and high reliability practices
- ❖ Develop a plan to comply with the new ISO standards

## *Steps to Success*

❖ **Step One - Research the standard** and supporting literature to familiarize yourself with the how's and why's of the change.

- The Joint Commission Sentinel Event Alert lists multiple resources for planning and implementation.
- [www.jointcommission.org](http://www.jointcommission.org)
- [www.StayConnected2014.org](http://www.StayConnected2014.org)



## *Steps to Success*

❖ **Step Two – Identify key stakeholders** from affected facilities and departments and **create a core team** to plan for and communicate the change.

- Nursing (Adult, Pediatric, Outpatient, Long Term Care)
- Purchasing / Supply Chain
- Distribution, Materials and Management
- Pharmacy
- Education
- Vendor

## *Steps to Success*

### ❖ **Step Three – Perform a Gap Analysis to identify existing deviations and opportunities.**

- List the overall strategic goal or initiative
- Identify the current state of practice (list all departments and individual equipment pieces used - make no assumptions)
- List each deficiency/opportunity identified
- Create an action plan for each identified deficiency/opportunity to bring it from current state to goal.

## *Steps to Success*

❖ **Step Four – Follow through** on the Gap Analysis and action plan with the team and have regular meetings to stay on track and ensure progress.

- Proactive approach with realistic deadlines
- Engage with the vendor to ensure appropriate crosswalk of supplies
- Troubleshoot barriers as they arise
- Get Hands-On with any new equipment as soon as possible
- Formulate an education plan and plan for follow up after implementation

## *Education Plan*

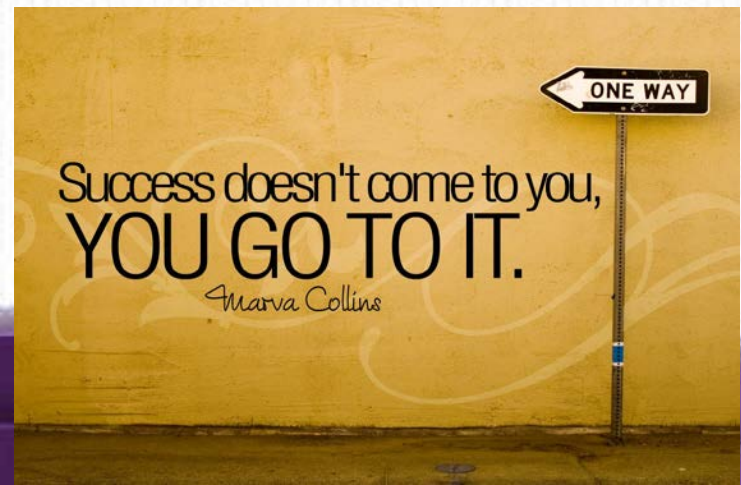
- Based on our product manufacturer, we do not anticipate availability of the new products until January
- Online education module – all nursing staff
- Hands on and Return Demonstration Competency – all nursing staff
- Incorporate into Orientation for all New Hires after the roll out
- Continue Safety Culture and High Reliability work



## *Steps to Success*

### ❖ **Step Five – Follow up** after implementation to ensure safety and success

- Round to ensure compliance and understanding
- Track and report any issues
- Continually review the ISO standards, engage with the vendors, and review best practices to mitigate inadvertent tubing misconnections.





# References

- **The Joint Commission: Managing risk during the transition to new ISO tubing connector standards, Sentinel Event Alert #53, August 20, 2014 (accessed September 5, 2014)**
- **Small bore connectors standards development timeline, Stay Connected 2014 website, <http://www.stayconnected2014.org/#meet> (accessed September 18, 2014)**
- **Connections Portfolio: Tubing misconnections self-assessment for healthcare facilities, ISMP and Baxter, [http://www.baxter.com/downloads/healthcare\\_professionals/clinical\\_center\\_of\\_excellence/baxterselfassessment.pdf](http://www.baxter.com/downloads/healthcare_professionals/clinical_center_of_excellence/baxterselfassessment.pdf) (accessed September 18, 2014)**
- **Executive Insights on Healthcare Technology Safety: See section on “Luer Connectors” and in the online Report Resources. AAMI and ECRI Institute, June 2014, <http://www.aami.org/aami-ecri/Tech%20Trends%202014.pdf> (accessed September 18, 2014)**

# Q&A



## On The Line To Answer Questions:

- **Ronald Wyatt, M.D. (The Joint Commission)**
- **Thomas J. Hancock (GEDSA)**
- **Peggi Guenter, Ph.D., R.N., FAAN (A.S.P.E.N)**
- **Mike Cohen, R.Ph., M.S. (ISMP)**
- **Amy Wilson, R.N., M.S.N., CPHQ (Sacred Heart Hospital, Pensacola, Florida)**
- **Sarah Amole, R.N., M.S.N. (Sacred Heart Hospital, Pensacola, Florida)**