REDUCING THE RISK

of Medical Device Misconnections

A presentation for HealthTrust members
March 26, 2021

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MIKE CUSACK

Executive Director, GEDSA

GEDSA MISSION

Promote patient safety worldwide

through ISO compliant

connectors.

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ISO 80369 SMALL BORE CONNECTOR STANDARDS

This effort is **NOT**:

- a company nor
- a GEDSA effort.

- It **is** an International Standards Organization (ISO) effort.


Tricia's story

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- Mission: to promote initiatives surrounding safe and optimal delivery and connectivity.
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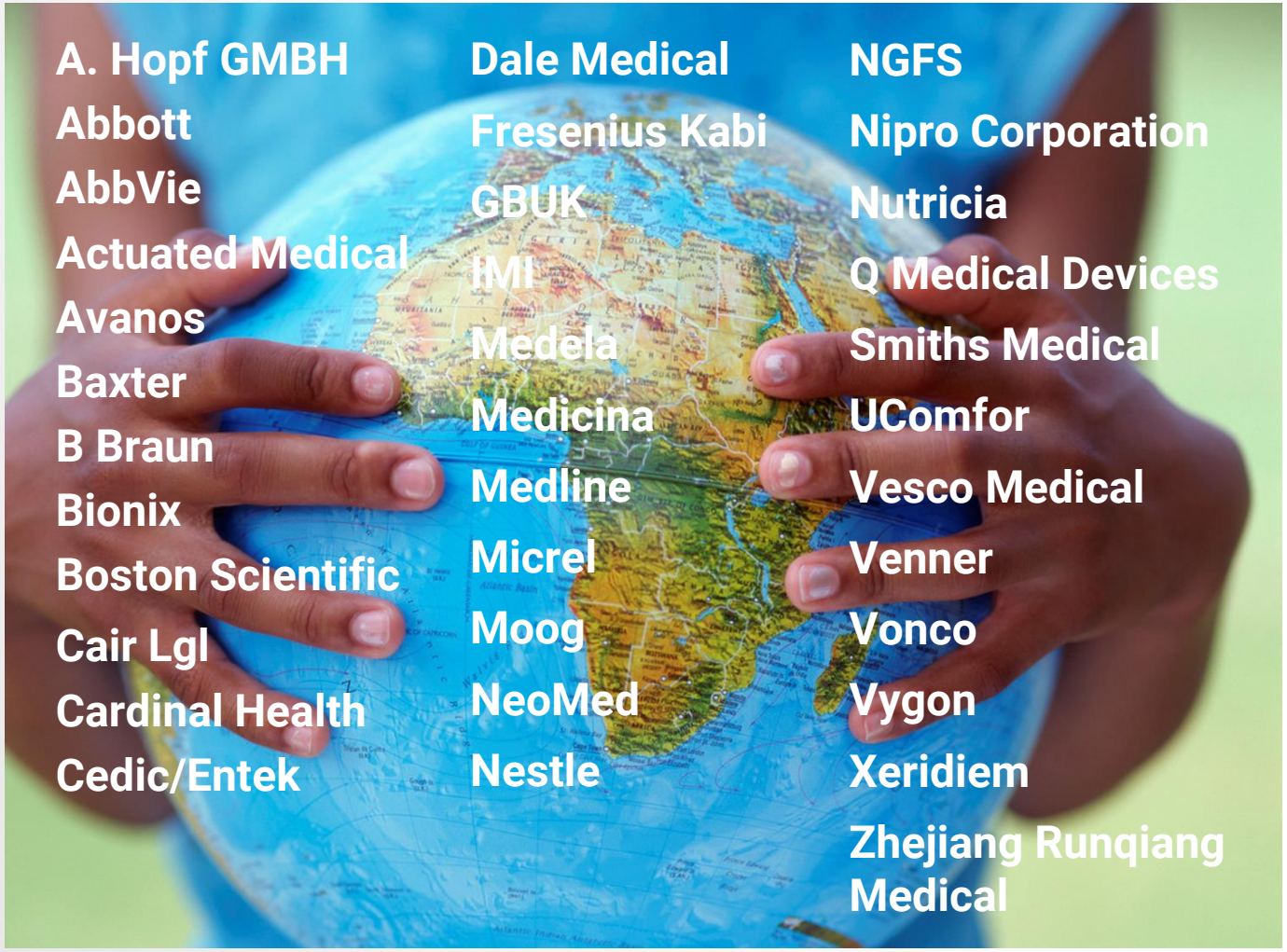
CONFLICTS OF INTEREST

- No conflicts of interest, either professionally or personally.

GEDSA MEMBERS



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SUPPORTING ORGANIZATIONS

AAMI
Advancing Safety in Medical Technology

AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

ASHRM
American Society for Healthcare Risk Management
safe and trusted healthcare

ashp
pharmacists advancing healthcare

aspen
Leading the Science and Practice of Clinical Nutrition
American Society for Parenteral and Enteral Nutrition

AVA

BRASPEN
SBNPE

Feeding Tube Awareness Foundation

HEALTHTRUST

ISMP
Institute for Safe Medication Practices

The Joint Commission

PREMIER

Medication Safety Collaborative

mni
Medical Nutrition International Industry

NPSF
National Patient Safety Foundation®

The Oley Foundation
Help along the way

vizient

ECRI Institute

JSPEN 日本臨床栄養代謝学会
JAPANESE SOCIETY FOR CLINICAL NUTRITION AND METABOLISM

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A BRIEF HISTORY OF STANDARDIZED CONNECTORS

- **1896** K.S. Luer, France, patents glass syringe with a tapered connection

- **Early 1900s**, hypodermic & IV products launched.

- **1930** F.S Dickinson patents the Luer-Lok™ connector

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RISE OF THE DISPOSABLE SYRINGE

- **1950s** a dramatic increase during US polio vaccine campaigns.
    - December 1961 Dr. Albert Weiner, 12 counts of manslaughter.
- **1960s** Abbott Labs, Baxter, and B Braun united behind Luer style connector
- **1978** ANSI Luer Taper Standard issued

STANDARDIZATION OF IV CONNECTORS

- **1988** USAF Base, Ramstein, Germany
- Blue Angels Air Show, a mid-air collision
- 70 spectators killed and 100s injured
- USAF and German EMTs responded
- Two different connectors: ***Rekord*** **vs.** ***Luer***

REDUCING THE RISK OF MEDICAL DEVICE TUBING MISCONNECTIONS

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ECRI TOP 10 TECHNOLOGY HAZARDS

- ECRI published "Top 10 Technology Hazards for 2012", a practical guide to identifying technology risks at health care facilities.
- The guide addresses 10 medical technologies that most frequently lead to patient injuries (and historically, malpractice lawsuits):
- Alarm hazards
- Exposure hazards from radiation therapy and CT
- Medication administration errors using infusion pumps
- Cross-contamination from flexible endoscopes
- **Inattention to change management for medical device connectivity**
- **Enteral feeding misconnections**
- Surgical fires
- Needlesticks and other sharps injuries
- Anesthesia hazards due to incomplete pre-use inspection
- Poor usability of home-use medical devices

http://www.krogerlaw.com/blog/2012/02/medical-technology-risk-management-ecri-institute-releases-top-10-hazards-guide/

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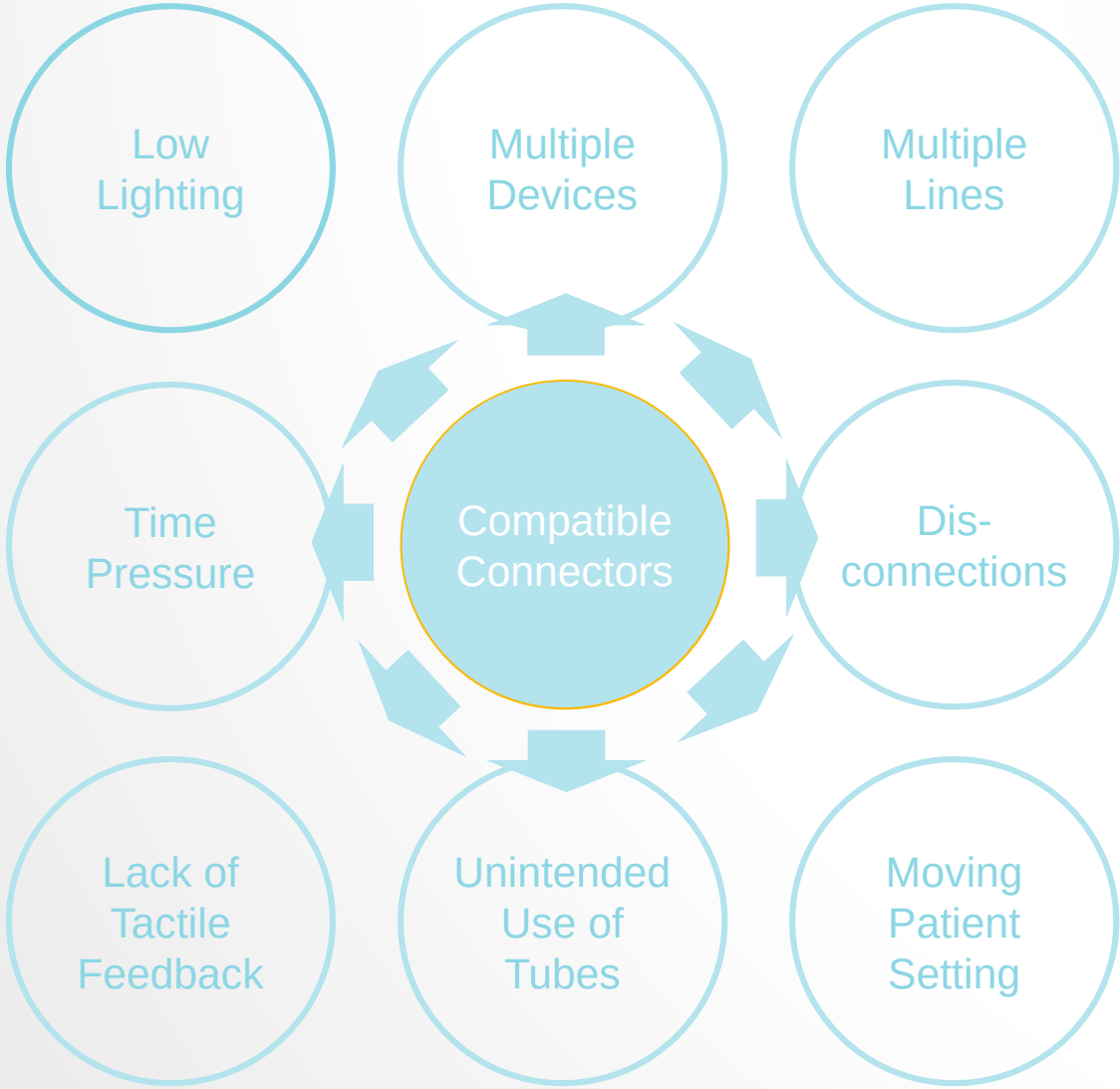
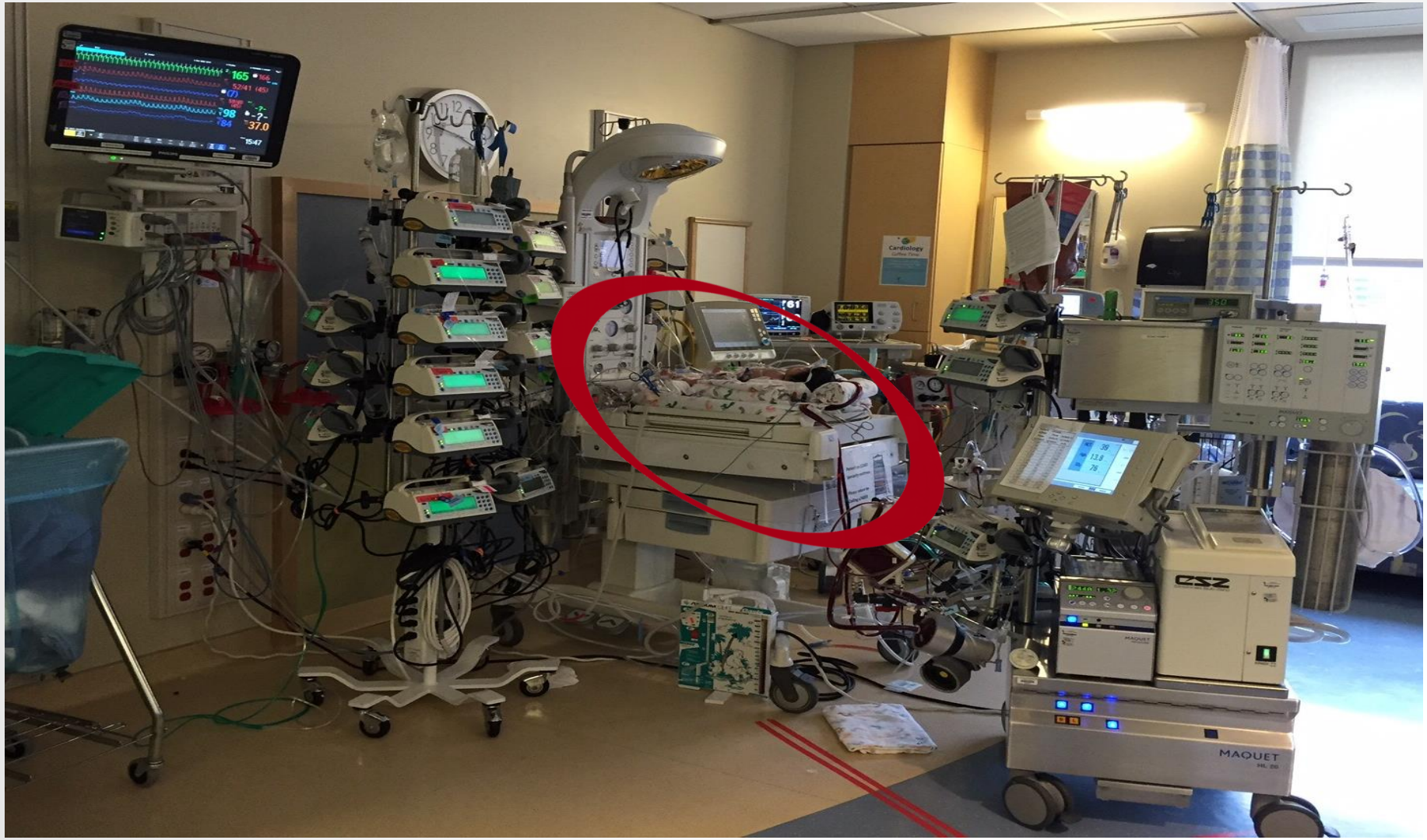
SIMMONS *ET AL.* 2010 LITERATURE REVIEW

- 116 Cases
  - 21 Died (18%)
  - 95 Survived (82%)
  - 84 of the 95 had at least 1 diagnosis reported 37/84 respiratory conditions including arrest (44%)
  - 16/84 had sepsis (19%)
  - 11/84 had neurological harm (13%)
  - 8/84 had renal impairment (9.5%)
  - 1/84 had hypersensitivity/hypercoagulopathy

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
- **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





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SUPPORTING STATEMENTS AND RECOMMENDATIONS

- FDA letter
- JC Sentinel Alert and Physician Leaders
- CMS
- ASPEN
- ISMP/ECRI

A Global Effort to Enhance Patient Safety

Stay Connected 2015

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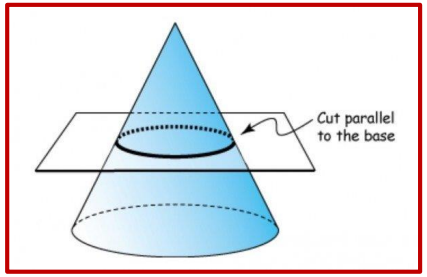
ISO DESIGN STANDARDS

Respirator					Intravascular
-2	-3	-4	-5	-6	-7

- **Requirements:**
- Not connectable with others in series
- Rigid or semi-rigid
- Passes Misconnection, Risk Analysis, Usability/Human Factors Testin
- Not connectable with Luer or needleless connector ports



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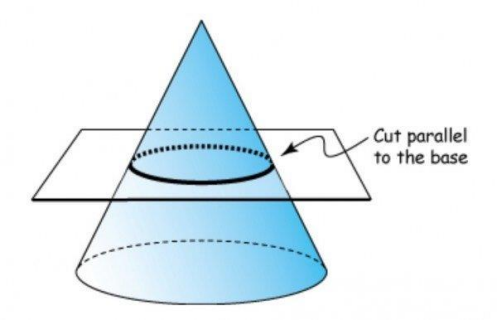
INTERNATIONAL STANDARDIZATION

- Increased awareness
- Action and focus by professional and regulatory organizations
- Purpose of ISO: prevent interconnectivity
- Implement “incompatibility by design” features



GLOBAL ADOPTION STATUS

Europe Leads Global Adoption of ISO 80369-3 connectors

North America
- ~ 30%
- Law (AB444) in CA effective July 1, 2016

Europe
- Approaching 100%
- UK, Netherlands, France, Italy, Belgium > 90% transitioned

Asia
- ~ 5% adoption
- 2020 for Japan
- China 2021

Australia/NZ
~ 80% adoption

South America
~ beginning

Eastern Europe, Middle East & Africa ~ 30%

* Adoption rates are only rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world

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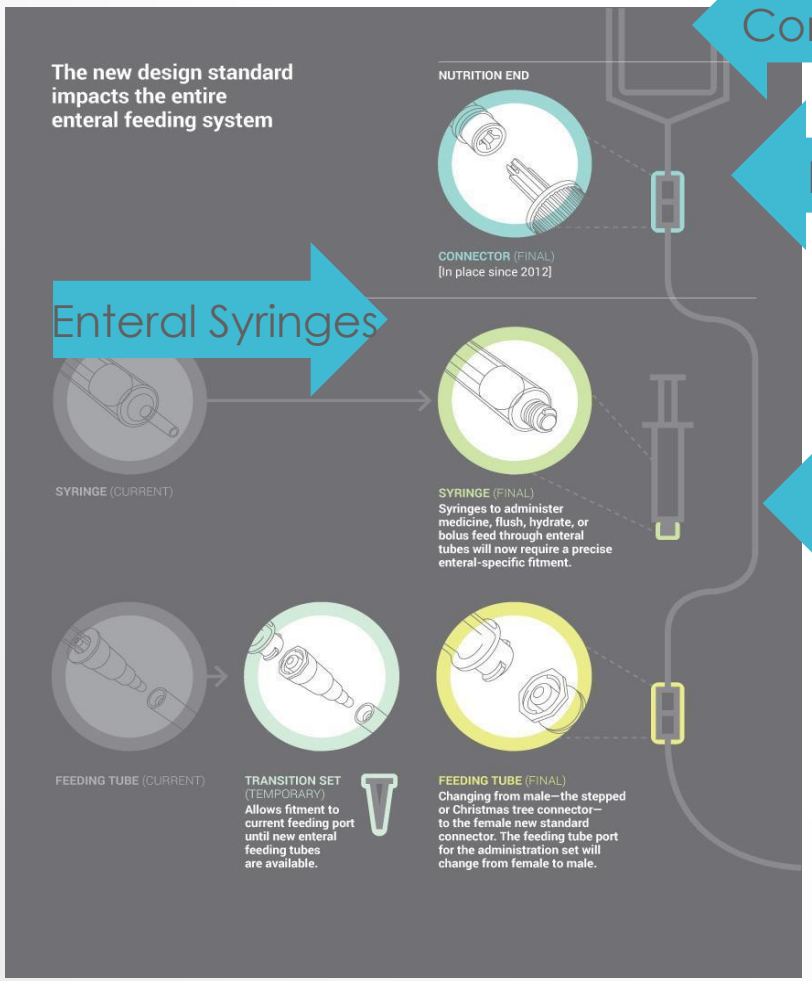
PRODUCTS AFFECTED



Completed

Feeding Set

Extension Set

Feeding Tube

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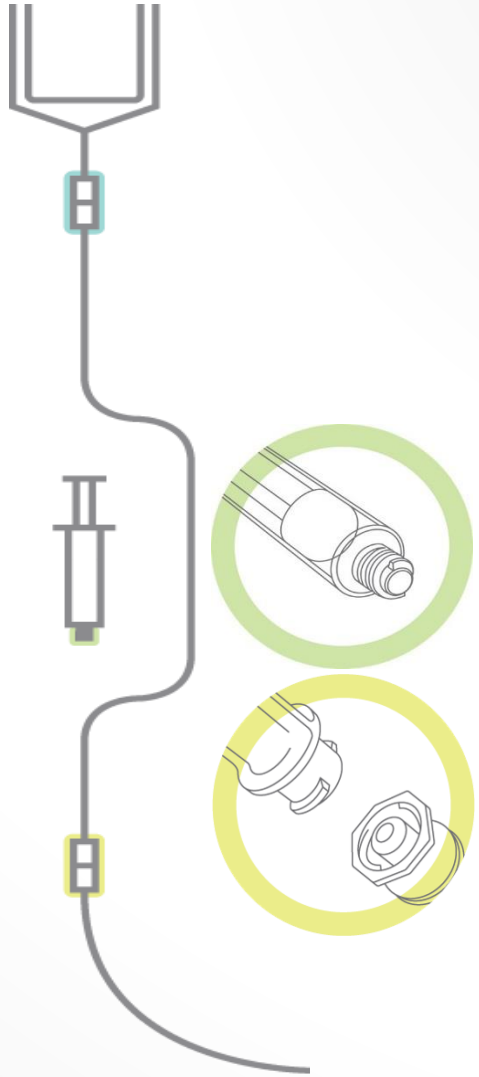
IDENTIFY PRODUCTS AFFECTED

A. Administration Sets

B. Syringes

C. Feeding Tubes

D. Pharmacy & Other Ancillary Devices



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ADMINISTRATION SETS

Transition Sets:

- administration sets have already converted

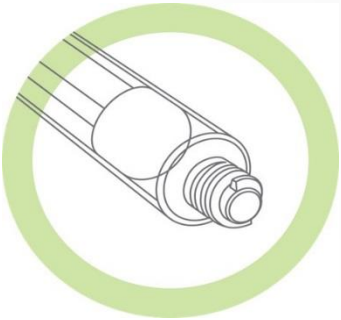
Types of Administration Sets

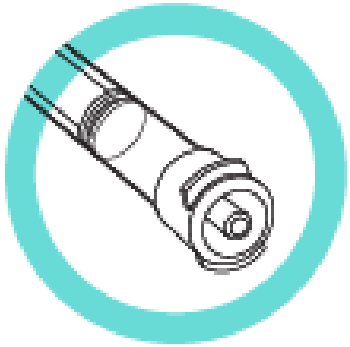
- Spike & Bag Pump Sets
- Gravity Feeding Sets
- Other Bolus Feeding Devices

SYRINGES USED FOR ENTERAL FEEDING

Types of syringes commonly used for feeding, flushing and administering medication

- Enteral/Oral Syringes (E/O syringes)
- Luer Slip Tip Syringes
- Catheter Tip Syringes
- Common size syringes (.5, 1, 3, 5, 6, 10, 20, 35, 60 mL)
- Safety Syringes
- **ENFit Tip Syringes** must be used with ENFit Feeding Tubes.





FEEDING TUBES AFFECTED

Types of tubes commonly used for feeding

- Gastrostomy (G-Tube)
- Low Profile Feeding tubes and corresponding extension sets*
- Nasograstric (NG-Tube)
- Nasojejunal (NJ-Tube)
- Gastrojejunal (GJ-Tube
- PEG Tube Y-Ports

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OTHER ITEMS AFFECTED

- Bottle fill caps
- Medication bottle adapters
- Fill Straws
- Syringe caps
- Tamper evident solutions
- Prefilled syringes
- Light protective solutions

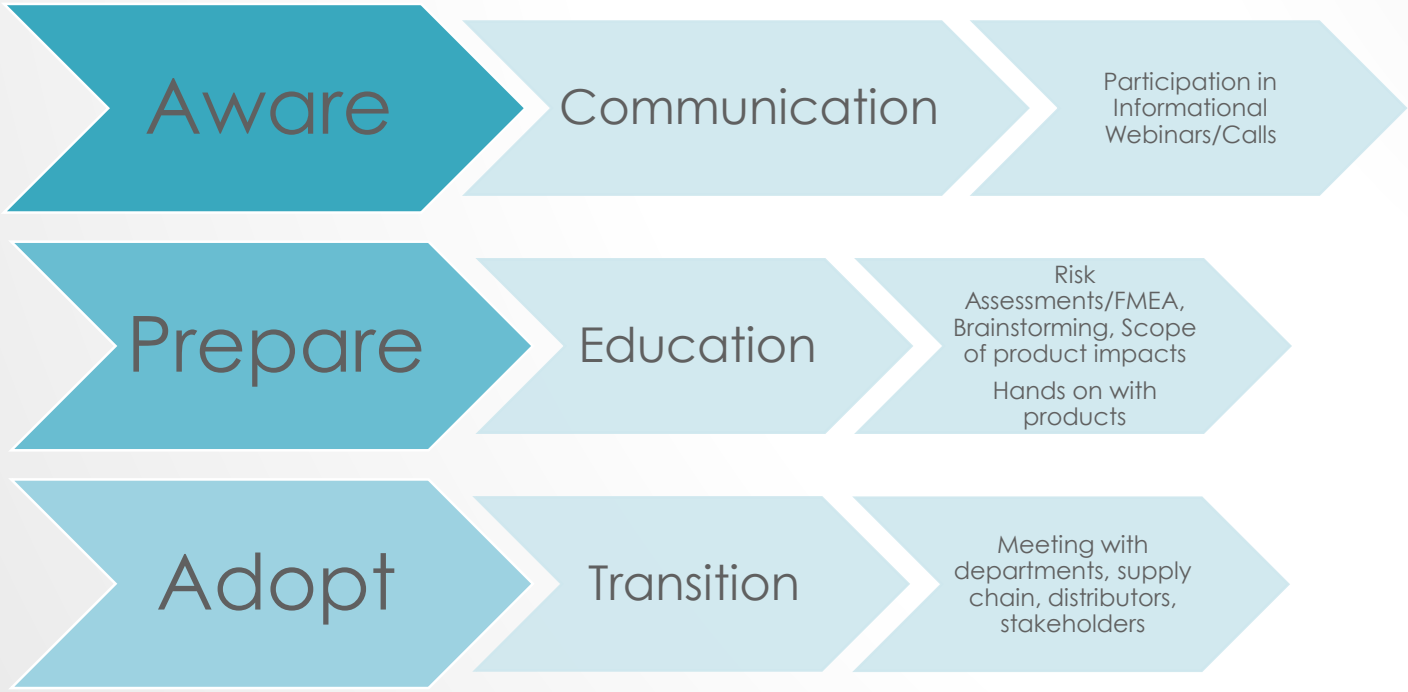
OFF LABEL USE – NO ISO COMPLIANT CONNECTORS

- Any devices not indicated for enteral feeding will NOT have an ISO compliant connector.
- Examples of off label feeding tubes
  - Foley Catheters
  - Red Rubber Catheters
  - Other Urinary Catheter

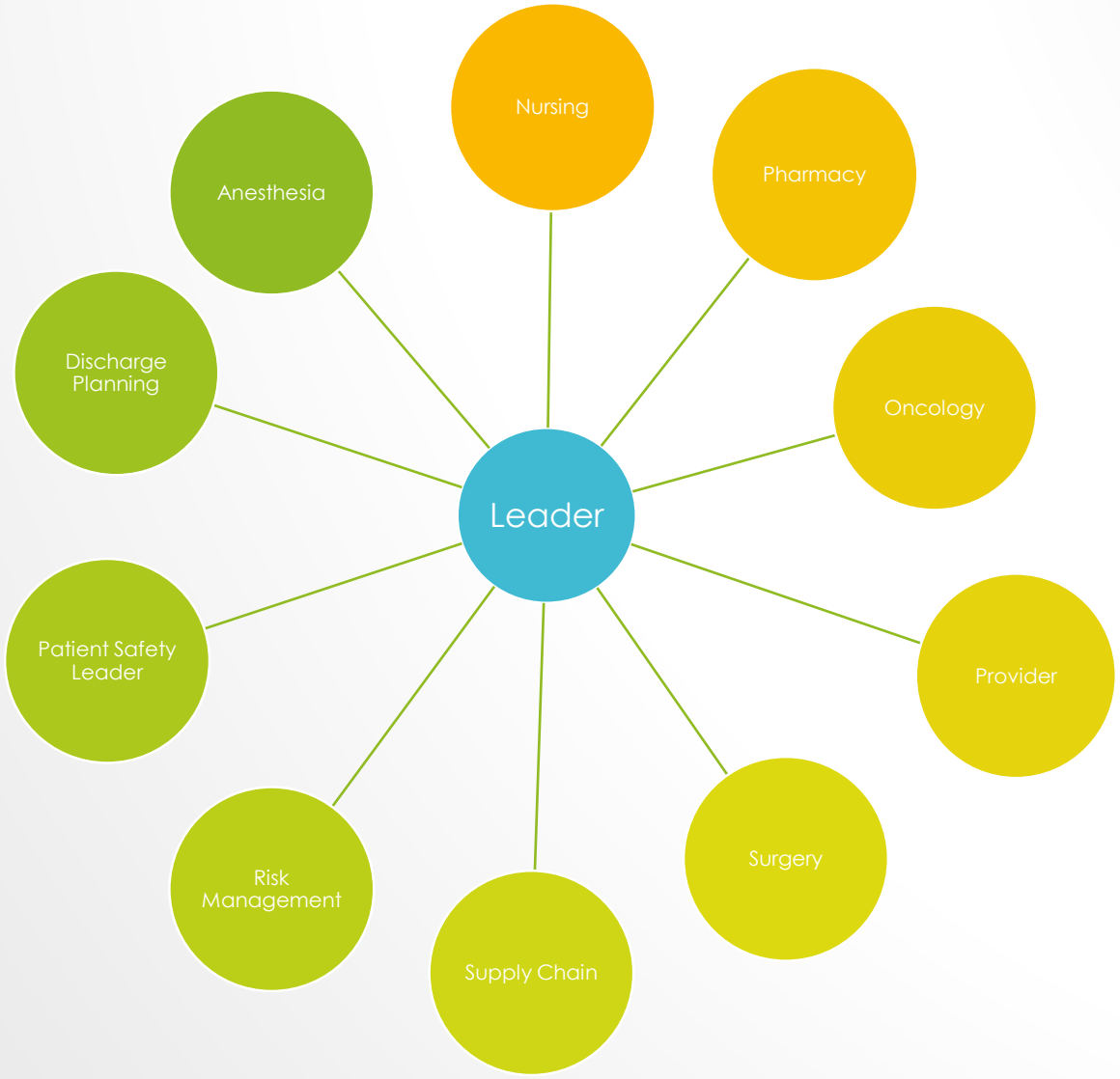
CLINICAL ADVISORY BOARD

- Practical advice on lessons learned from experienced peers
- Multi-disciplinary board with 12-15 representatives from nursing, physicians, pharmacists, dietitians, and others
- Match with the best available advisor
- Publishing monthly tech tips on StayConnected.org

PROCESS AND TIMELINE

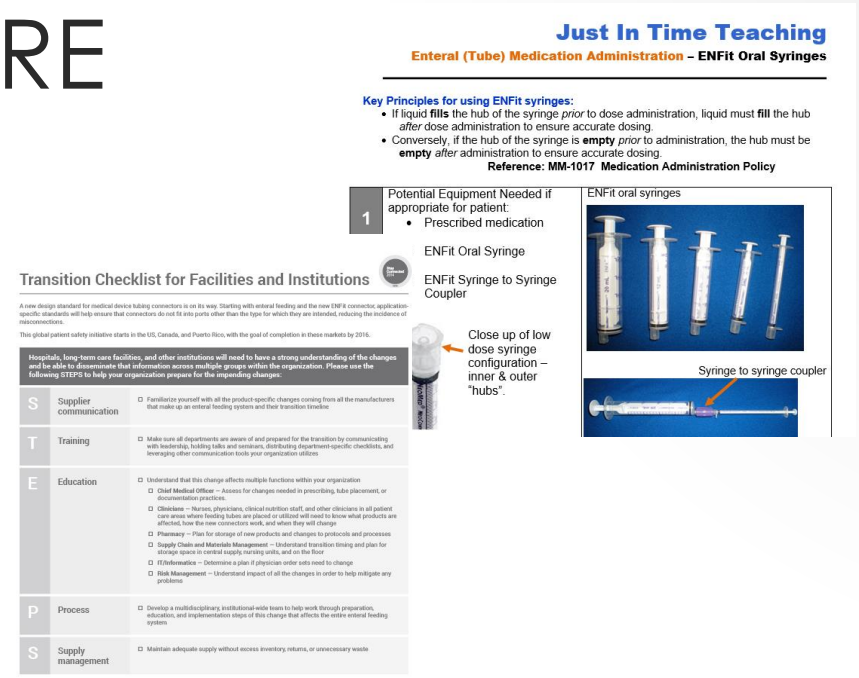


INTERNAL TEAM AWARENESS



PREPARE

- List of affected products
- Checklists to prepare for every part of the hospital
- Crosswalk of changing products
- Educational materials
- Continue building the tool kits you find helpful



Just In Time Teaching

Enteral (Tube) Medication Administration – ENFit Oral Syringes

Key Principles for using ENFit syringes:

- If liquid **fills** the hub of the syringe *prior* to dose administration, liquid must **fill** the hub *after* dose administration to ensure accurate dosing.
- Conversely, if the hub of the syringe is **empty** *prior* to administration, the hub must be **empty** *after* administration to ensure accurate dosing.

Reference: MM-1017 Medication Administration Policy

1 Potential Equipment Needed if appropriate for patient:

- Prescribed medication

ENFit Oral Syringe

ENFit Syringe to Syringe Coupler

Close up of low dose syringe configuration – inner & outer "hubs".

ENFit oral syringes

Syringe to syringe coupler

Transition Checklist for Facilities and Institutions

A new design standard for medical device tubing connectors is on its way. Starting with enteral feeding and the new ENFit connector, application-specific standards 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 global patient safety initiative starts in the US, Canada, and Puerto Rico, with the goal of completion in these markets by 2016.

Hospitals, long-term care facilities, and other institutions will need to have a strong understanding of the changes and be able to disseminate that information across multiple groups within the organization. Please use the following STEPS to help your organization prepare for the impending changes:

S	Supplier communication	☐ Familiarize yourself with all the product-specific changes coming from all the manufacturers that make up an enteral feeding system and their transition timeline
T	Training	☐ Make sure all departments are aware of and prepared for the transition by communicating with leadership, holding talks and seminars, distributing department-specific checklists, and leveraging other communication tools your organization utilizes
E	Education	☐ Understand that this change affects multiple functions within your organization ☐ **Chief Medical Officer** – Assess for changes needed in prescribing, tube placement, or documentation practices. ☐ **Clinicians** – Nurses, physicians, clinical nutrition staff, and other clinicians in all patient care areas where feeding tubes are placed or utilized will need to know what products are affected, how the new connectors work, and when they will change ☐ **Pharmacy** – Plan for storage of new products and changes to protocols and processes ☐ **Supply Chain and Materials Management** – Understand transition timing and plan for storage space in central supply, nursing units, and on the floor ☐ **IT/Informatics** – Determine a plan if physician order sets need to change ☐ **Risk Management** – Understand impact of all the changes in order to help mitigate any problems
P	Process	☐ Develop a multidisciplinary, institutional-wide team to help work through preparation, education, and implementation steps of this change that affects the entire enteral feeding system
S	Supply management	☐ Maintain adequate supply without excess inventory, returns, or unnecessary waste

Current Product Description	MFO Item #	Current Lawson #	Current UOM	UOM Factor	New Product Description	New Mfg. #	New Lawson #
Tube Feeding Gastrostomy 14Fr LF	0020212	232495	Ea	1	Tube Feeding ENFit 14Fr LP	0080818	232459

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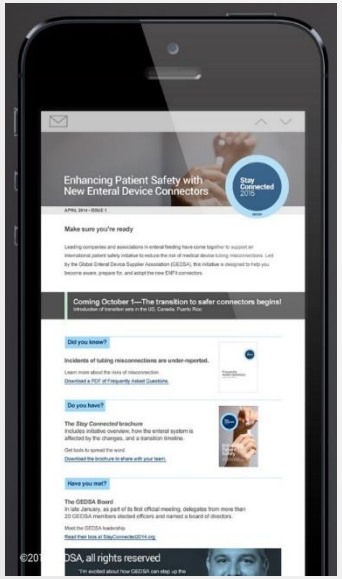
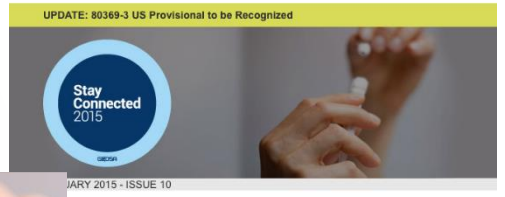
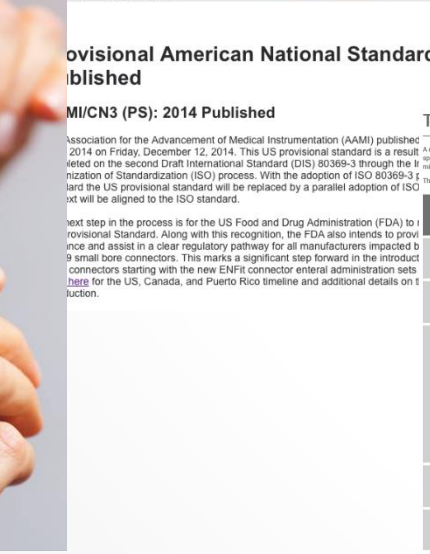
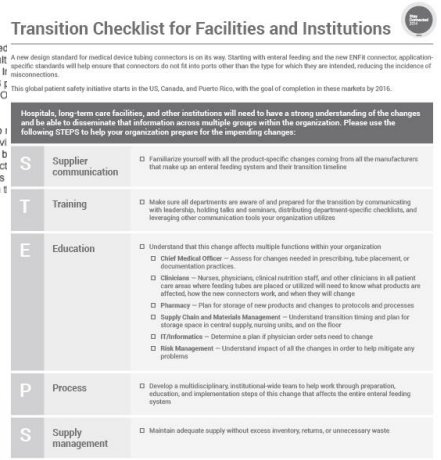
BROCHURES, PRESENTATIONS, FAQS & CHECKLISTS
WWW.STAYCONNECTED.ORG









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SUPPORTING ARTICLES & RECOMMENDATIONS

1. **The Joint Commission** issues "Sentinel Event Alert, **Issue 36**: Tubing misconnections- a persistent and potentially deadly occurrence to increase awareness of tubing misconnection errors" AND **Issue 53:** Managing risk during transition to new ISO tubing connector standards
2. **Association for the Advancement of Medical Instrumentation (AAMI)** publishes "ISO 80369-1 Small bore connectors for liquids and gases applications" and is recognized by the FDA
3. **The Food and Drug Administration (FDA)** publishes a guidance on "Safety Considerations to Mitigate the Risks of Misconnections with Smallbore Connectors Intended for Enteral Applications"
4. **Institute for Safe Medication Practices (ISMP)** publishes Medication Safety Alert" ENFit Enteral Devices are on their way… Important safety considerations for hospitals"
5. **Center for Medicare & Medicaid Service (CMS)** addresses State Survey Agency Directors on "Luer Misconnection Adverse Events"
6. **ECRI Institute** releases "Critical Notice–Avoid Fatal Misconnections with ENFit-compliant Feeding Tube Connectors"
7. **American Society for Parenteral and Enteral Nutrition (ASPEN)** publishes "A.S.P.E.N. Supports Major Medical Device Changes for Improved Patient Safety"
8. **American Journal of Health-System Pharmacy (ASHP)** publishes "Transition to ENFit enteral devices: Special challenges for pediatric institutions"
9. **British Association for Parenteral and Enteral Nutrition (BAPEN)** published "ISO 80369-3: IMPORTANT UPDATE – ENFit Implementation"
10. **National Health Services (NHS)** publishes a patient safety alert "Stage One: Warning Managing risks during the transition period to new ISO connectors for medical devices "

For full references and articles visit StayConnected.org

11. **ISO**/TC 210 - IEC/SC 62D/ Joint Working Group 4, Small bore connectors Date: 2017.03.04: Guideline for the implementation of medical products using small bore connectors specified in the ISO 80369 series

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Thank you!

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