Learning Objectives

- Review background of Tubing Misconnections issue
- Explain why new small bore connector design standards are needed
- Describe challenges with dose accuracy of low doses (< 2.0mL) and the ENFit Low Dose Tip Syringe Solution
- Review timeline needed to effectively implement and transition new connector design

Your speakers today

Debora Simmons, PhD,RN,CCNS,FAAN
Associate Professor, UTHealth

Tom Hancock, MBA
Executive Director, GEDSA

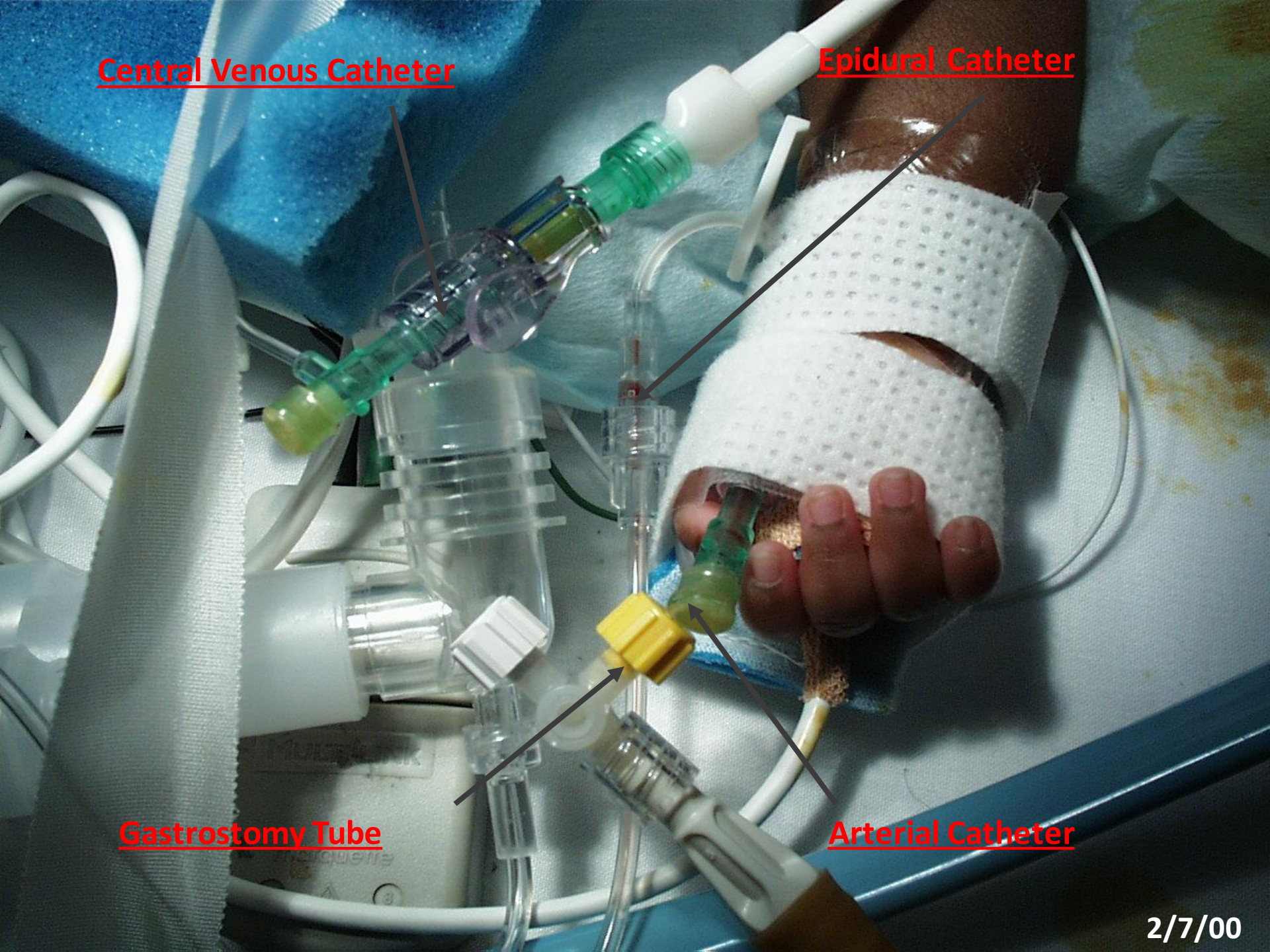
TUBING MISCONNECTIONS: A PREVENTABLE ERROR AND AVOIDABLE FATALITY

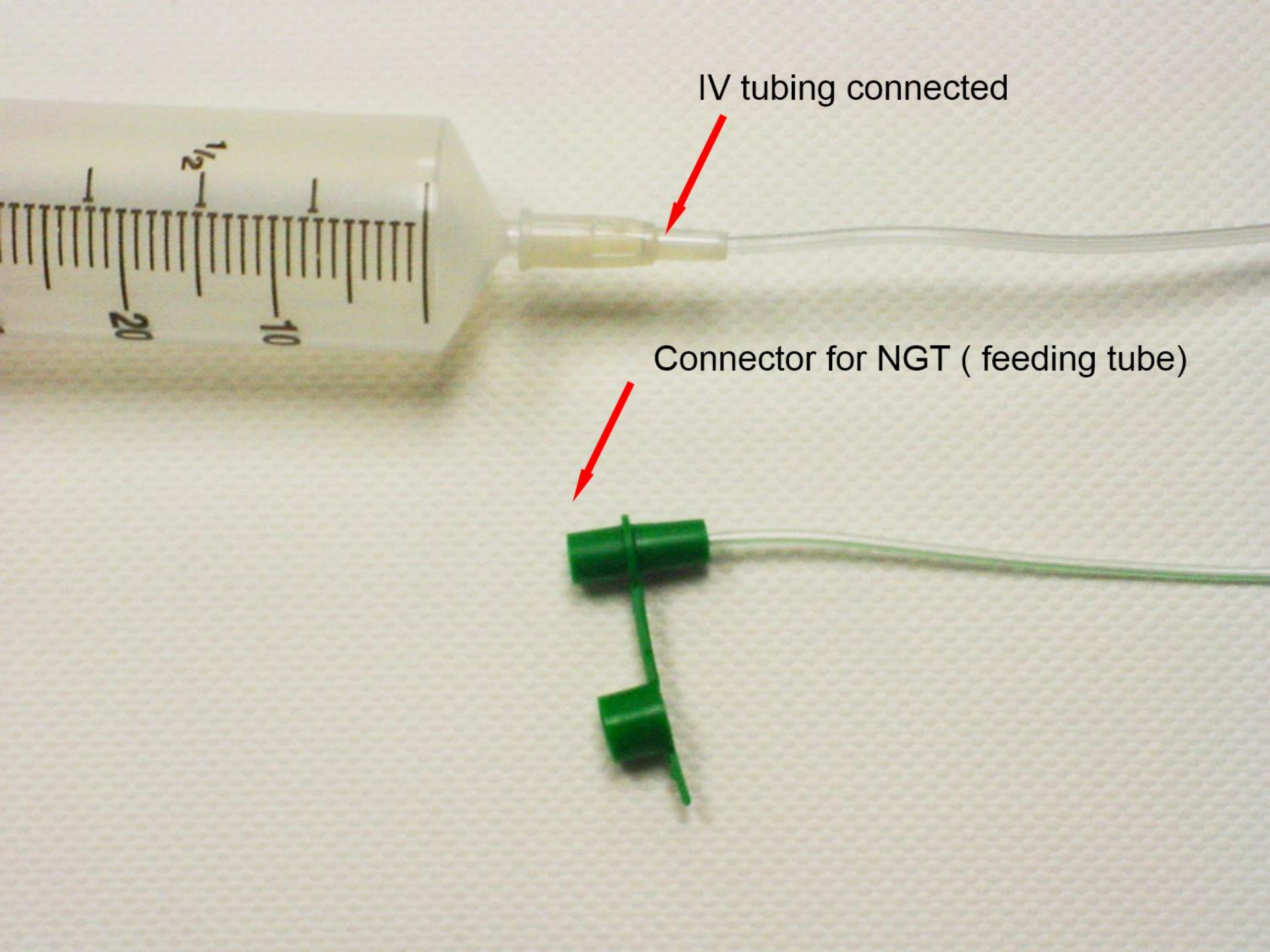
Debora Simmons PhD RN CCNS FAAN
UT Health

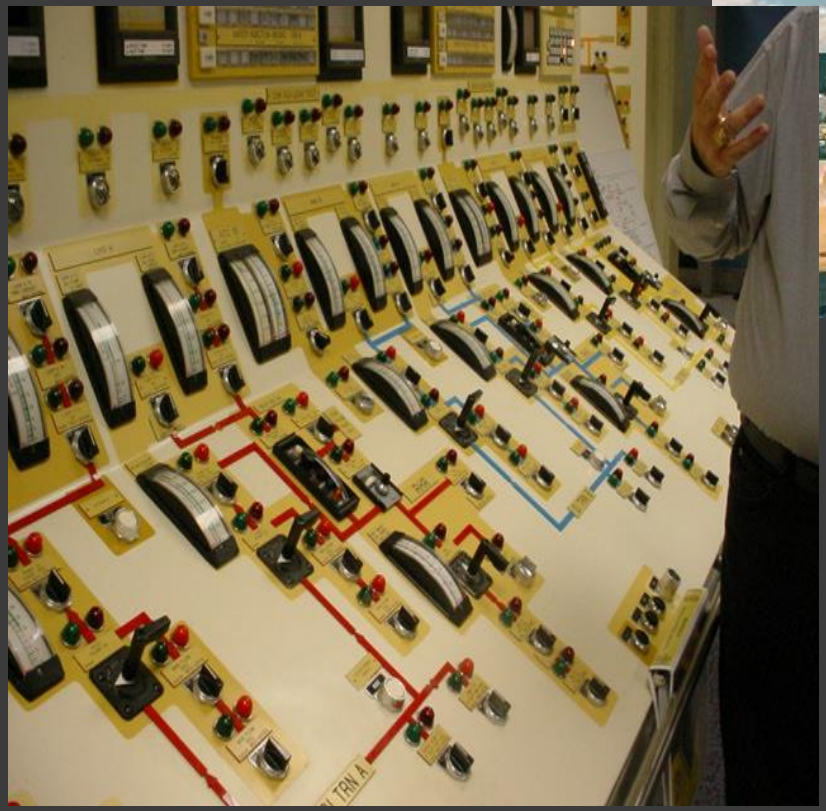
Disclosure

I have no commercial financial relationships to disclose.

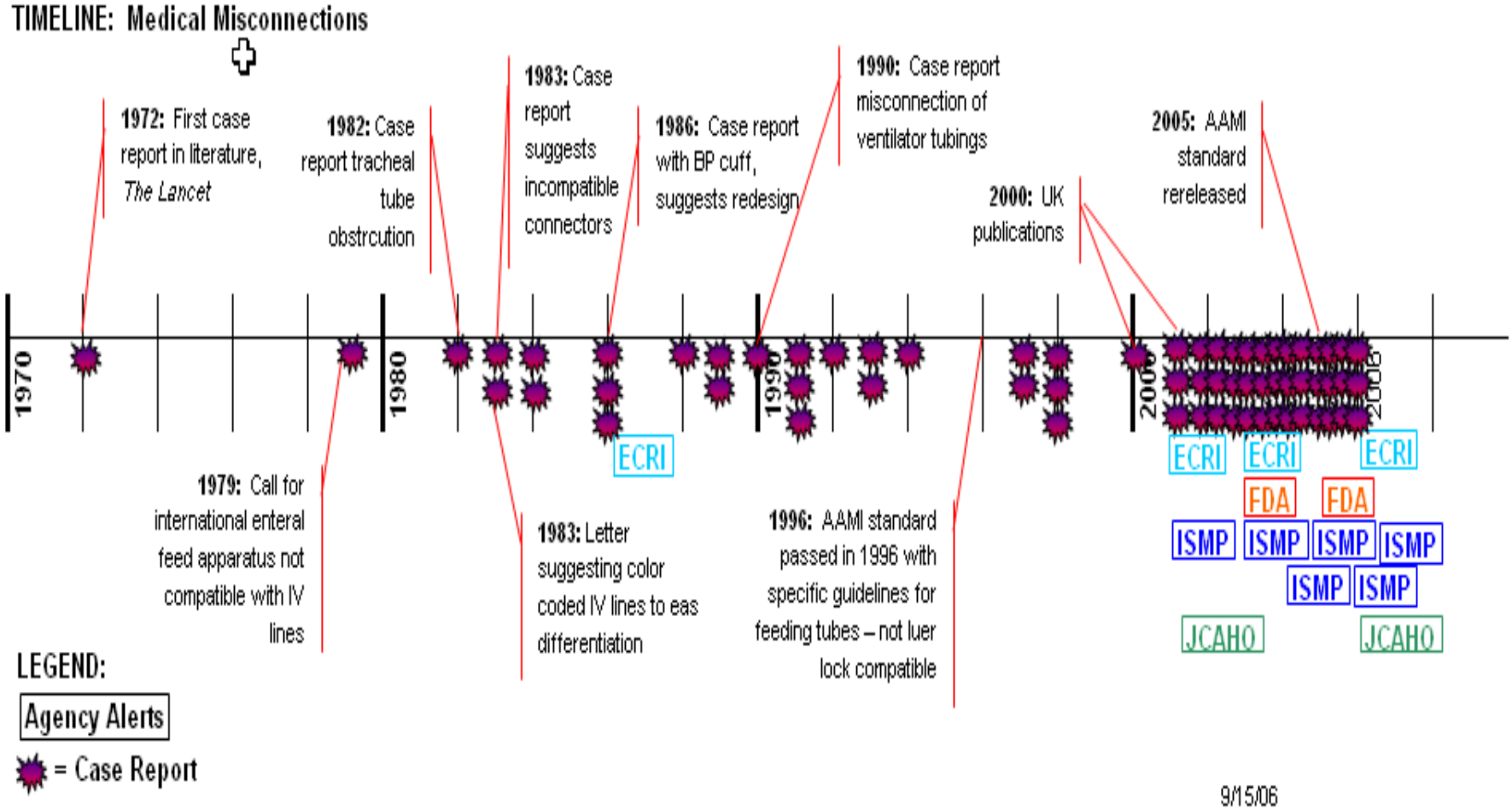
The opinions expressed in this presentation are solely my own.


Central Venous Catheter
Epidural Catheter
Gastrostomy Tube
Arterial Catheter
2/7/00


IV tubing connected
Connector for NGT (feeding tube)



Background to 2005



How many systems have universally fitting Luer connectors ?

- Intrathecal systems
- Gastrointestinal
- Genitourinary
- Drainage systems
- Cardiovascular
  - Arterial
  - Hemodynamic
  - Venous
- Driving gases
  - Pneumatic compression boots
  - Automatic Non invasive blood pressure
- Intravenous systems
- Respiratory systems
  - Ventilators
  - Breathing treatments

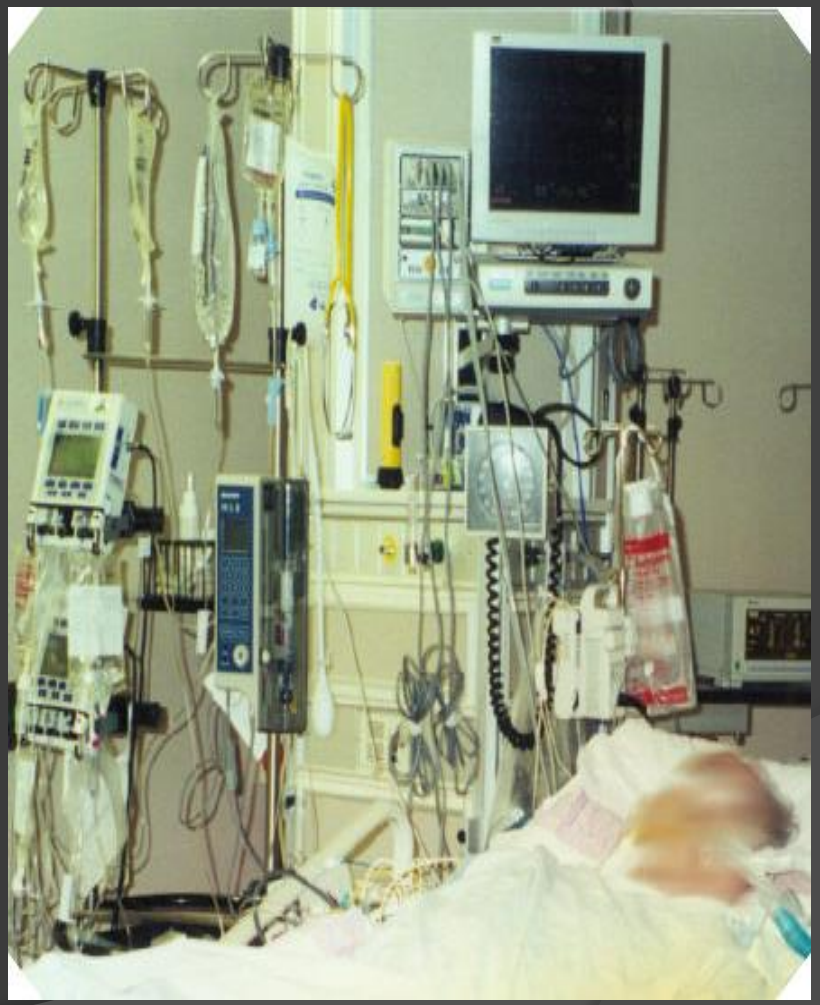
Tubing Misconnections: Normalization of Deviance

Case reports
N =116
Adult (N=60)
Child/infant (N=30)
Not Specified (NS) (N=26)

Patient Outcome from 116 cases
Death (N=21)
Survival:
- Hypersensitivity and Hypercoagulopathy reaction (N=1)
- Septicemia/sepsis (N=16):
  - 2 with neurologic damage
  - 2 with respiratory arrest
  - 33 with hypoxia
  - 1 with seizure & hypoglycemia
  - 5 with intracranial hemorrhage
- Renal impairment (N=8)
- Respiratory arrest/distress (not listed above) (N=2)
- Neurologic damage (not listed above) (N=2), 1 with blindness & deafness
- No harm, or outcome not given (N=12)

Connecting Tubing - a high-risk activity

- Infusion and monitoring systems in healthcare are physiologically not compatible
- Infusion systems rely upon a single, universal connector - the luer tip connector
- Routine tasks such as connecting tubing are at risk for “automatic mode errors”
- Healthcare is not designed for safety



Human Factors: Error Modes

- Automatic Mode
  - Slips
  - Lapses
- Non Automatic Mode
  - Mistakes

Automatic Mode:

Slips - errors that occur during familiar actions and are governed by familiar impulses incorrect execution of a planned action occur when you automatically do something that you didn't mean to do

Human Factors Issue

- In “automatic mode” errors are made without the participants knowledge
  - Locking the keys in the car
  - Dialing the wrong number
  - Putting the milk in the cabinet and cereal in the refrigerator

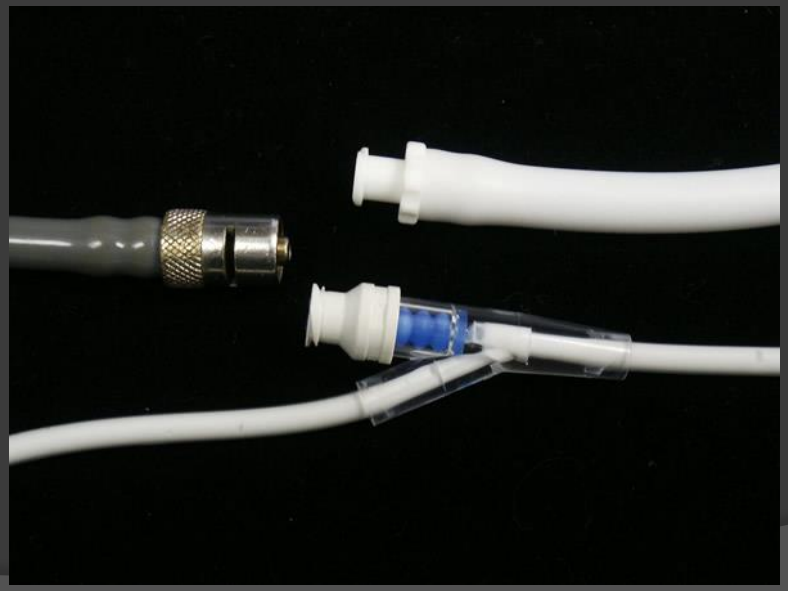
Automatic Mode Errors

- Are effortless and rapid
- Are failures of actions going as intended
- Occur in common and familiar functions in familiar surroundings
- Thinking is under “attentional control” – we only pay attention when there is a change
- Are usually not detected by the participant

Reason 1990

Examples of Slips with Redesign in Healthcare

- Free flow intravenous tubing
- Needle-less systems
- Double checks



Error is Inevitable Because of Human Limitations

- Limited memory capacity
- Limited mental processing capacity
- Negative effects of stress - Tunnel vision
- Negative influence of fatigue and other physiological factors
- Limited ability to multitask
- Flawed teamwork

The New York Times

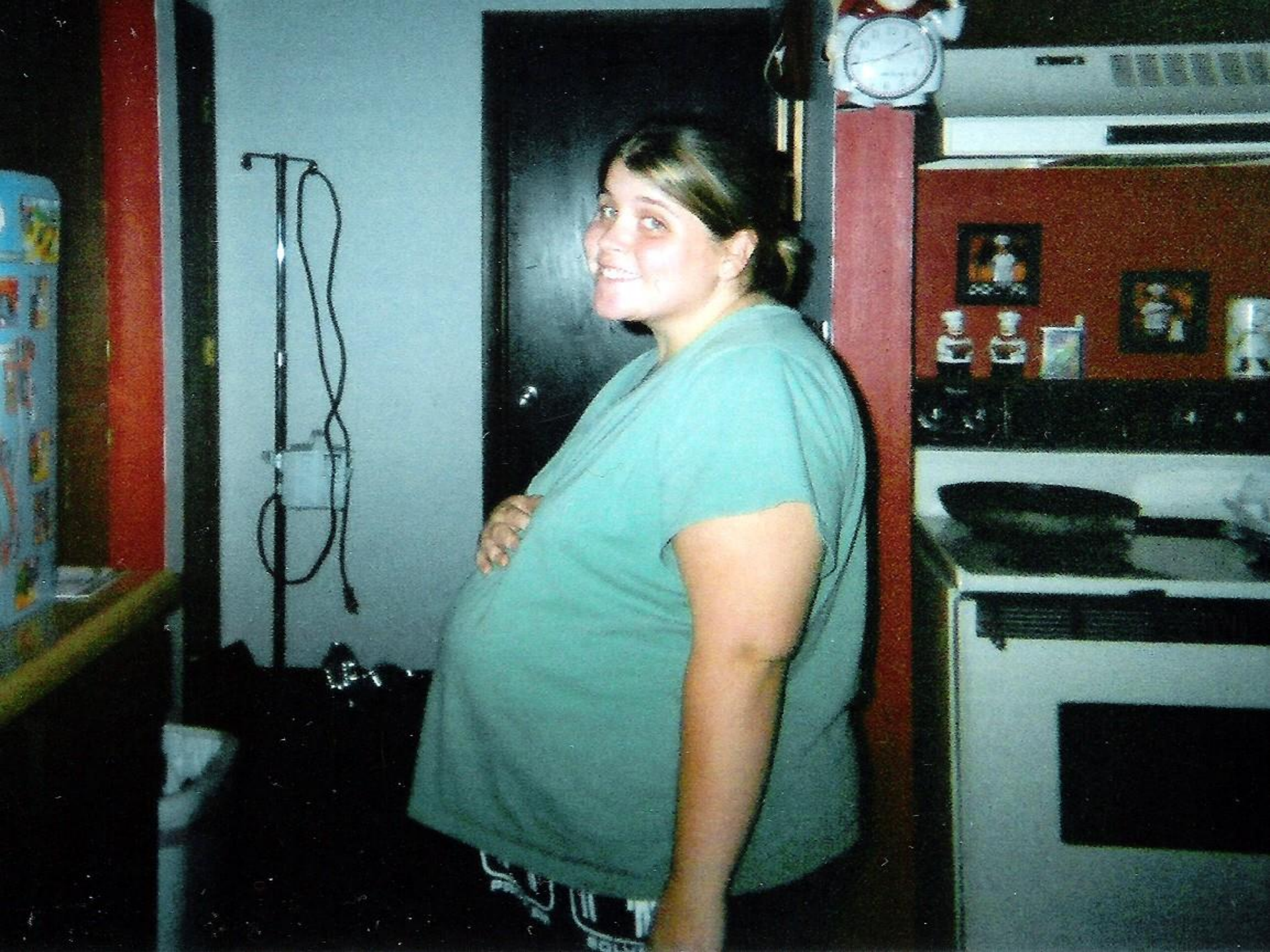
MONEY & POLICY

U.S. Inaction Lets Look-Alike Tubes Kill Patients

By GARDINER HARRIS AUG. 20, 2010

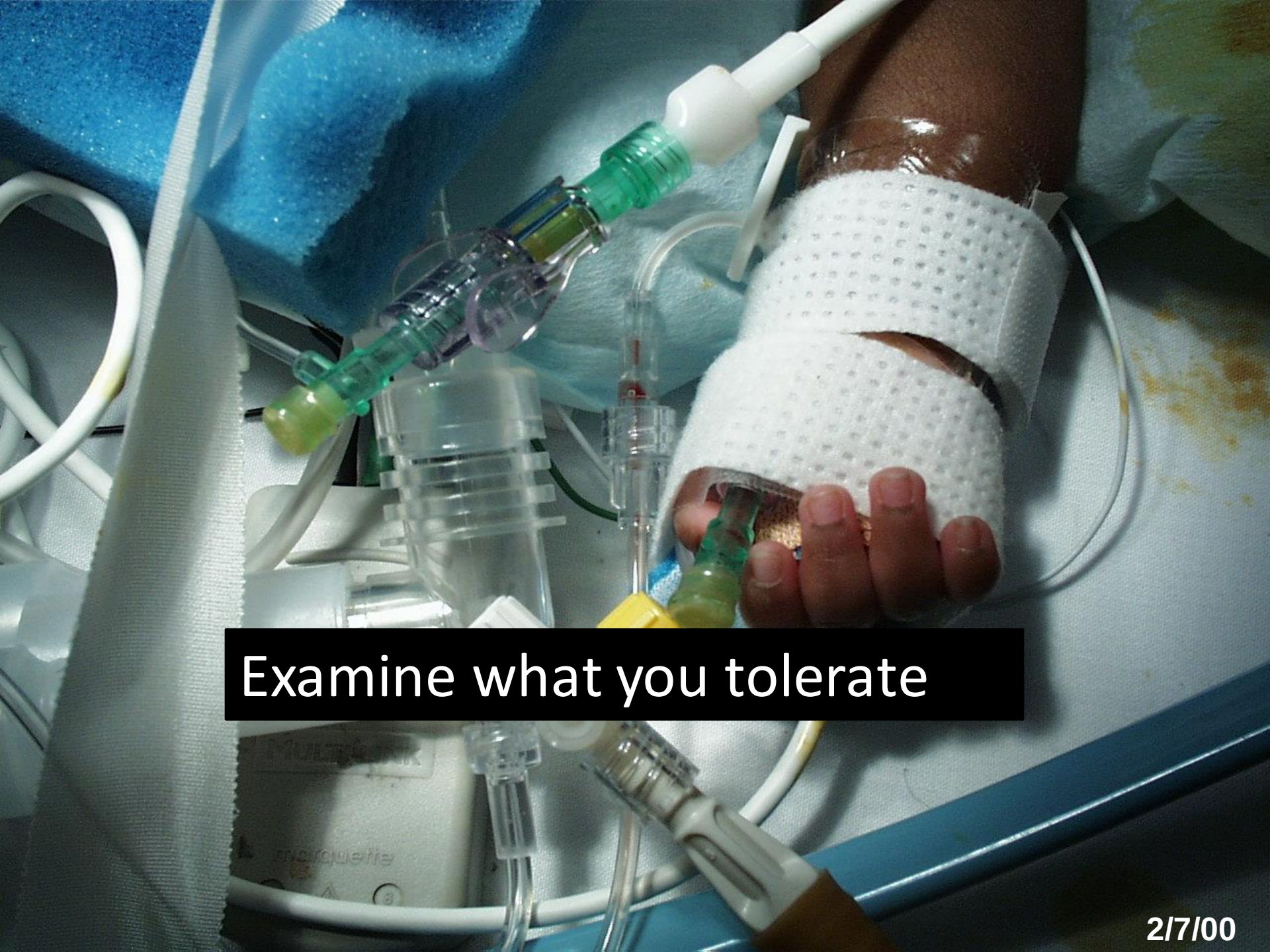
http://www.nytimes.com/2010/08/21/health/policy/21tubes.html?_r=0 retrieved March 1, 2016

Johannah Back of Las Vegas, with her daughter, Chloe, who almost died in 2006 in a mix-up of feeding and intravenous tubes. John Locher for The New York Times



The Facts

- We know without a doubt this is a safety hazard to patient death
- We know it is present in almost every healthcare setting
- Every major safety organization has supported this change
- We have been aware of this for over ten years
- We have not changed it in the healthcare setting to date
- People are still dying from this error
- It is past time to fix this
- We live with what we tolerate


Examine what you tolerate
2/7/00

ISO STANDARDS
GEDSA
ENFIT
STAY CONNECTED

Tom Hancock
GEDSA

GEDSA

Unite. Connect. Deliver.

MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity

GEDSA Members

Abbott
A. Hopf
Alcor Scientific
Amsino
Bard
Baxter
B Braun
Boston Scientific
Cair Lgl
Cedic/Entek
Codan
Cook Medical
Corpak
Dale Medical
Degania
Enteral UK
Fresenius Kabi
Halyard
Intervene
Medela
Medicina
Medline
Medtronic
Moog
NeoMed
Nestle
Nutricia
Qosina
Smith's Medical
UComfor
Vesco Medical
Vygon
VR Medical/Kentec
Xeridiem

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

Feeding Tube Awareness Foundation

HEALTHTRUST

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

The Joint Commission

MedAssets

MEDICATION SAFETY COLLABORATIVE

Novation

NPSF
National Patient Safety Foundation®

The Oley Foundation
Help along the way

PREMIER

Ineffective Attempts Demanded a Comprehensive Solution

2006

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

The Joint Commission issued a Sentinal Alert Initiating the ISO standard, CA legislation & public outcry for change

Stay Connected 2015

GEDSA

A Global Effort to Enhance Patient Safety

Stay Connected 2015

GEDSA

ISO Design standards developed for system-specific applications

80369 Series

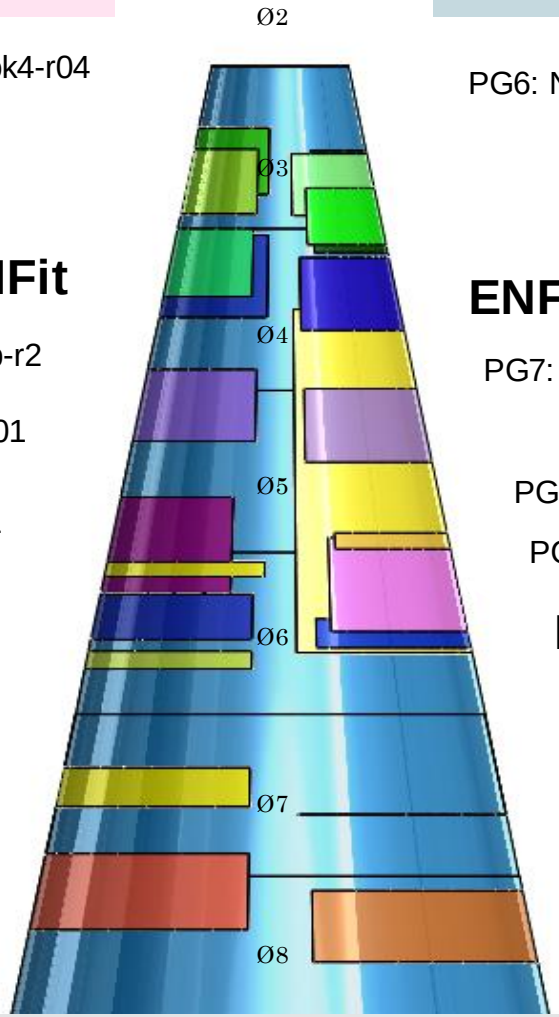
-1 General requirements

Respiratory	Enteral	Urological	Limb Cuff	Neuraxial	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 Testing
- Not connectable with Luer or needleless connector ports

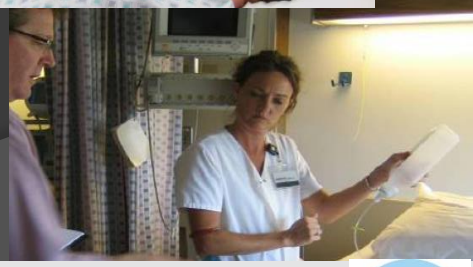
ISO Connector Dimension Allocation Diagram



Significant Testing Conducted to Verify & Validate Enteral Standard Design

Testing & Assessments

- Clinical Assessment
  - 20 Clinicians (Physicians, Nurses, Pharmacists)
- Usability/Human Factors
  - 53 US Clinicians (including 15 NICU)
- Misconnections Assessment
- Syringe Accuracy Report
- User Survey – 35 respondents in 3 European mkts
- Acceptability and Suitability Study
  - 48 Clinicians (including neonatologists in 6 European Markets
- Reverse orientation usage – UK reverse Luer
  - Millions of patients over nearly 10 years



Design standards for system-specific applications start with enteral

ENFit™

80369-3

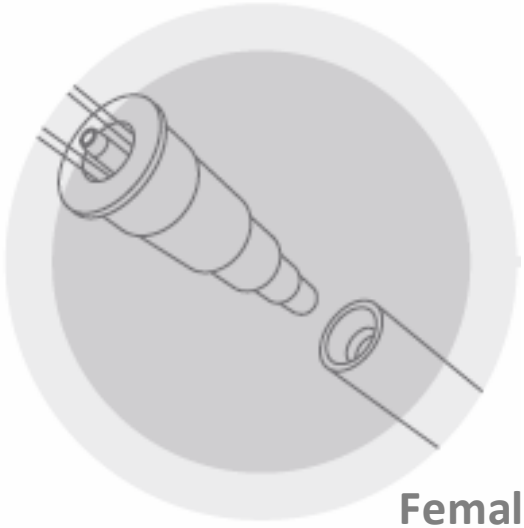
Stay Connected 2015

GEDSA

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

CURRENT

Male Stepped or "Christmas Tree" Connector from Administration Set

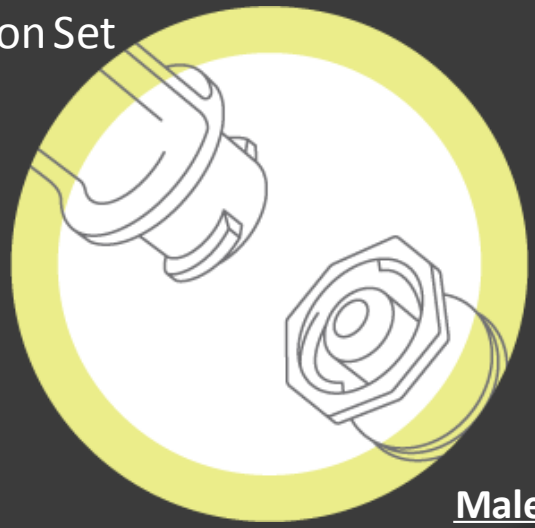


Female Feeding Tube Port

NEW

ENFit

Female ENFit Connector from Administration Set



Male ENFit Connector for Feeding Tube

TRANSITION SET

ENFit Transition Connector

- Temporary fitment
- From new ENFit connector to current feeding port

Check with your supplier regarding Transition Connectors from ENLock to ENFit

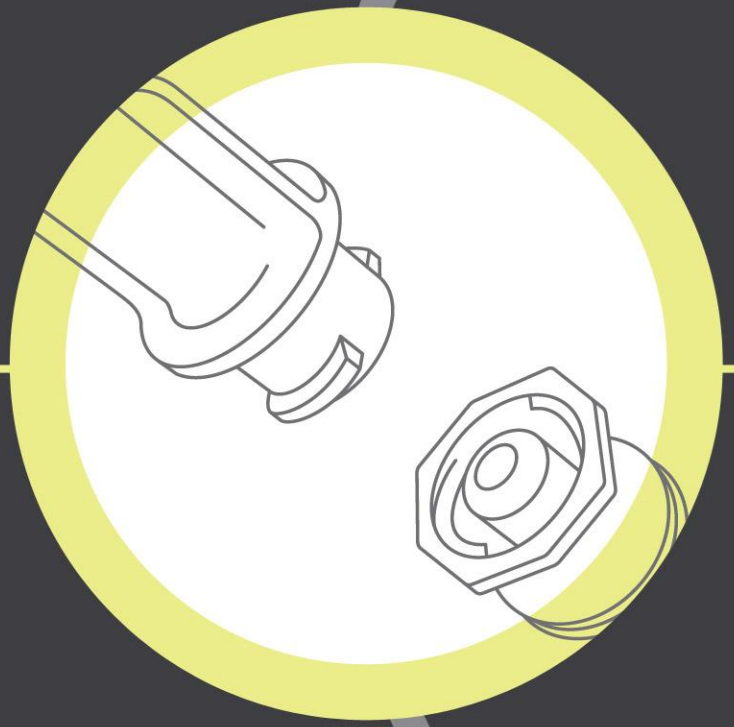
GOAL: Eliminate the Long Term Need for adapters

Stay Connected 2015

ADMINISTRATION SET

From Male Stepped Connector to Female ENFit:

- Pump Set
- Gravity Set
- Other Bolus Feed or Venting Devices



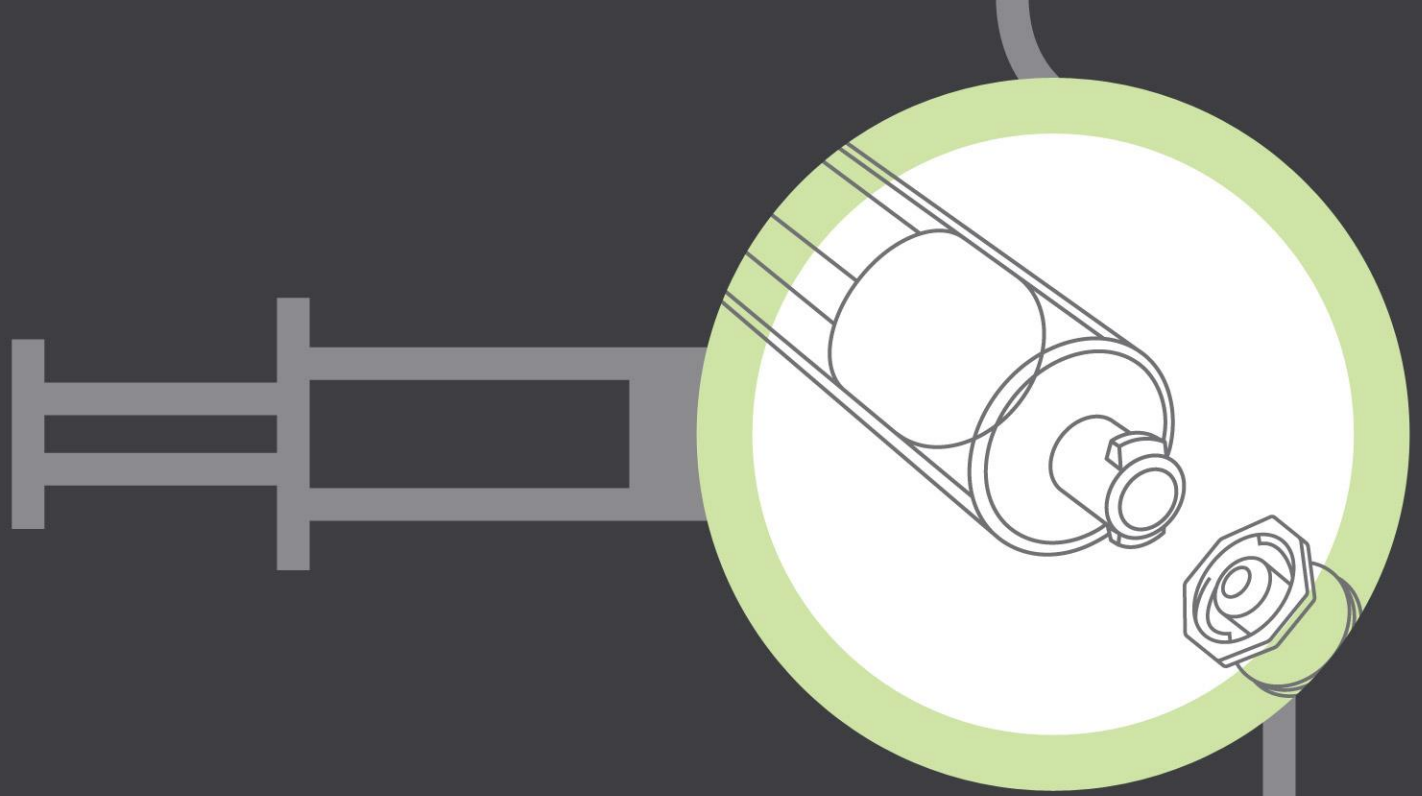
FEEDING TUBE

From Female Flexible Port to Male ENFit:

- NG Tubes
- G Tubes
- Low-Profile Extension Sets
- J-Tubes

Stay Connected 2015

GEDSA



SYRINGES

From oral, catheter, or Luer tip to enteral-specific fitment:

- Administer Medicine
- Flush
- Hydrate
- Bolus Feed

Stay Connected 2015

GEDSA

Dose Accuracy Concerns

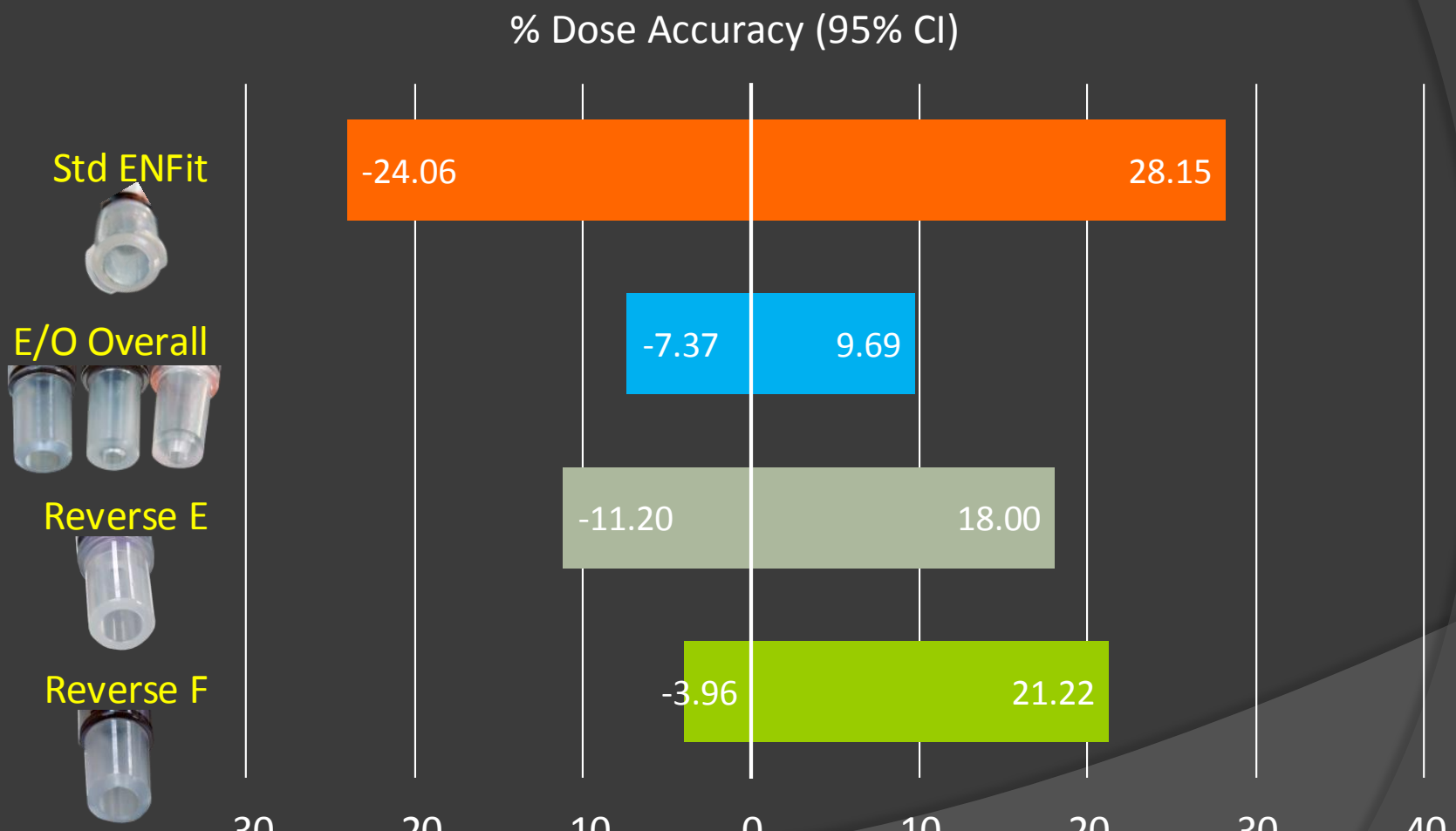
- Clinicians:
  - Clinicians have raised concerns on dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation
  - Clinicians and pharmacists indicated dosing accuracy expectation of ± 10% a target volume of 0.2 mL *(when delivered using a 1 mL syringe)*
- Industry:
  - There is no current standard (ISO, AAMI, ASTM, EN) dosing accuracy requirement or specification for oral/enteral syringes
  - Dosing accuracy is not a standard test performed by syringe manufacturers, therefore no baseline data exists for comparison

Dosing Accuracy Testing

- Performance Testing conducted by an independent external test lab
- Syringes with maximum volume of 5 mL and below may require a "low dose tip" ENFit® connector design to satisfy the dosing accuracy target
- GEDSA members collaborated to evaluate the following syringes to deliver an accurate dose level within +/-10% for small doses:
  - Existing enteral/oral (male tip)
  - Female Luer lock (reverse system used in the UK)
  - Proprietary syringes currently marketed
  - Standard ENFit tip
  - Proposed ENFit Low Dose Tip

All data assessed by GEDSA members was consolidated and submitted to the FDA to support the 510(k) for the low dose tip design

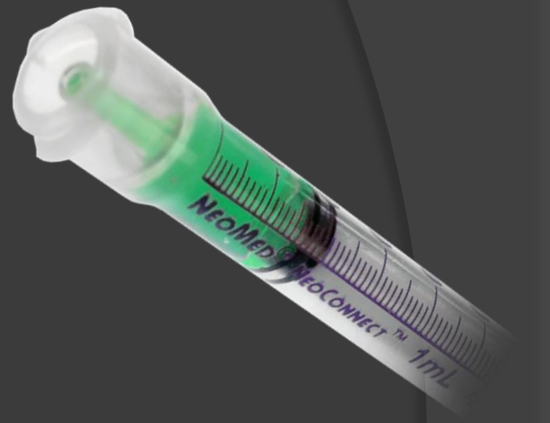
Dose Accuracy of Common Enteral/Oral Tip Syringes



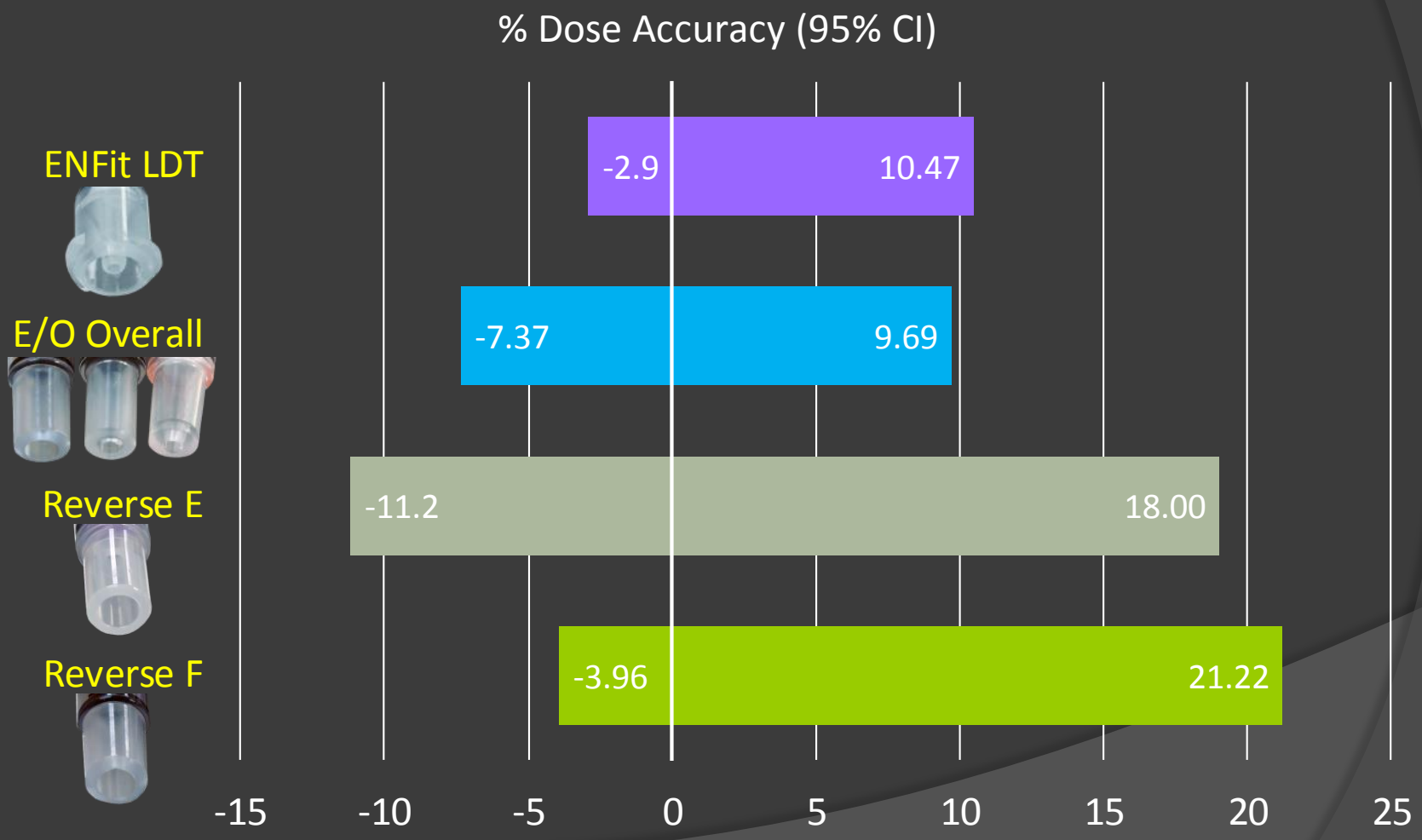
Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe.

Proposed ENFit® Low Dose Tip Syringe

- The ENFit Low Dose Tip *(LDT)* Syringe was designed to specifically address dose accuracy concerns.
  - Design proposed for inclusion into ISO 20695 enteral device standards
- LDT is: Standard ENFit female syringe tip with an internal tip lumen.
  - Mimics functionality of traditional male oral/enteral syringe designs
- Orientation/configuration is similar to Luer lock syringes*



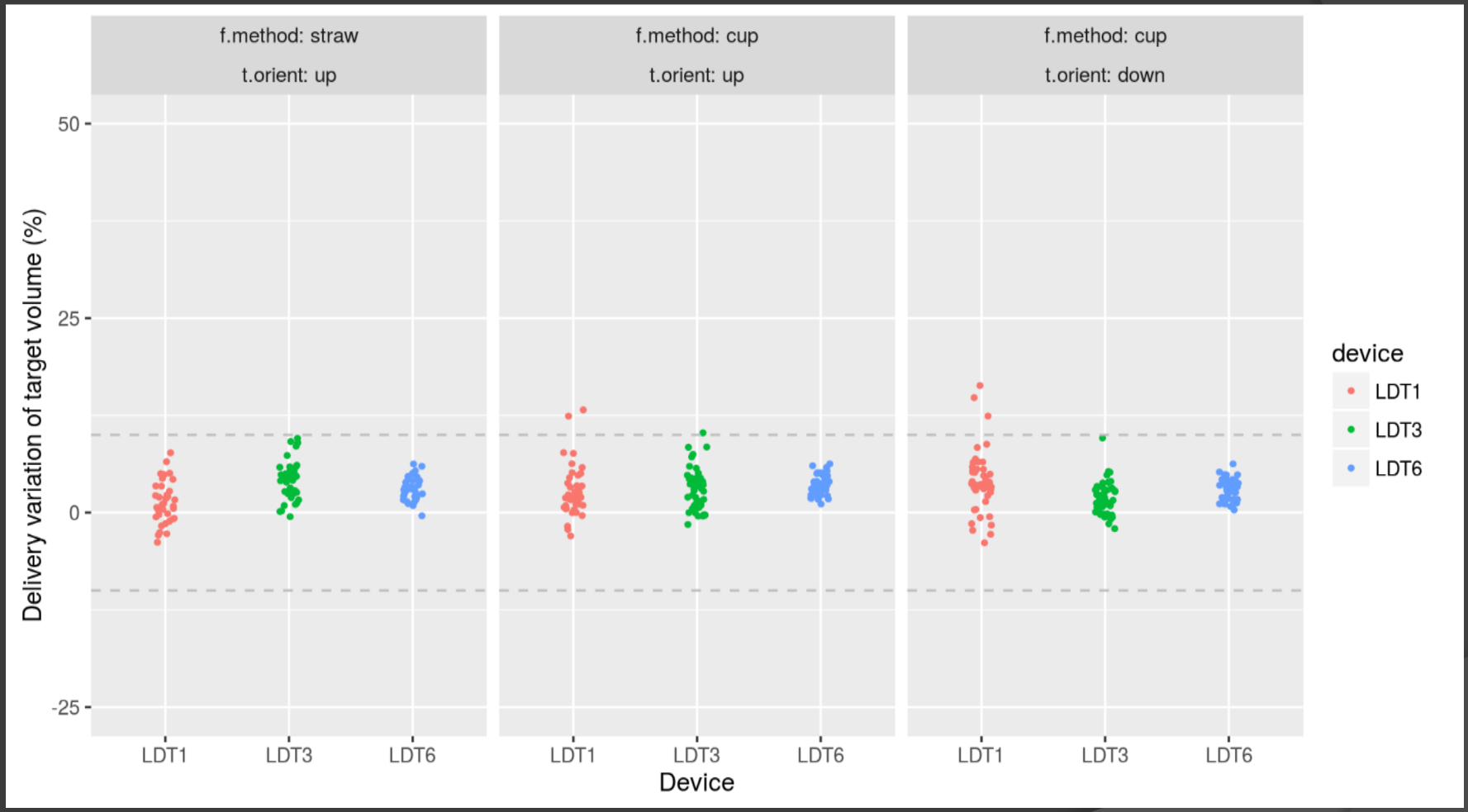
Dose Accuracy of ENFit® Low Dose Tip vs. Common Enteral/Oral Tip Syringes



Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe.

Dosing Accuracy Summary

All Test Sizes of Low Dose Syringes (1, 3, 6mL)



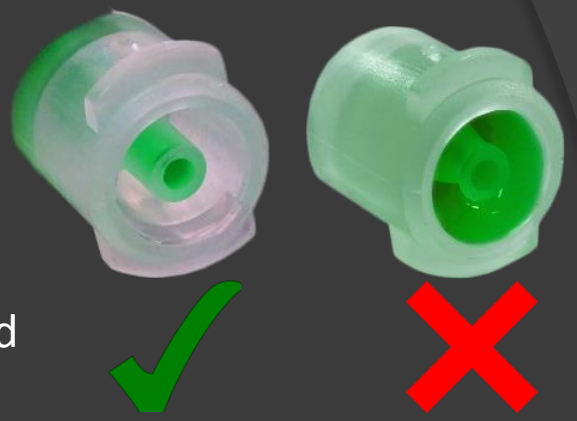
As syringe size and target dose increase, the dosing accuracy improves because the displacement as a proportion of the target dose decreases.

Usability Testing Top Level Summary

- 150+ respondents worldwide representing pharmacy, nursing and caregivers testing the ENFit® LDT vs. current practice
- No significant differences for syringe use when water or a thicker liquid (pepto bismol) was filled and administered
- No significant difference for syringe use between responses of Pharmacist, Nurses, or Caregivers
- No significant difference for syringe use when filling from a dose cup when:
  - Capping
  - Doing nothing
  - Wiping the syringe tip or
  - Tapping the syringe tip

Best Practices

- Removal of Residual Fluid
  - The LDT male lumen behaves similarly to the male nozzle on a standard (male) syringe.
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to remove fluid



- Method of filling the syringe (cup fill vs straw/adapter fill)
  - Straw/adapter fill method is more accurate than cup fill method due to less potential for residual fluid on syringe to transfer to feeding tube.

- Depending on orientation of syringe and feeding tube during filling and disconnection excess fluid may flow:
  - Toward syringe creating residual fluid on syringe that can transfer to the feeding tube.
  - Into the feeding tube or fluid may flow back out of feeding tube.

Low Dose ENFit® Syringe Conclusion

Performance Test Results (when used as instructed):

- Dose Accuracy range of -2.90% to +10.47% (95% CI)
- Substantially equivalent to standard orientation (male) enteral/oral syringes
- Performs better than Reverse Orientation (female tip) syringes.
- Use of an adaptor (such as a straw) provides better performance than a cup fill

Misconnection Risk Assessment:

The ENFit Low Dose Tip mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit that outweighs the risk of its use.

Usability:

No significant difference vs. current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)

Note: Further consideration will need to be given to training and awareness relative to flicking and the benefits of draw up devices

BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
tel: 201-847-6800
fax: 201-847-4850
www.bd.com

BD

Helping all people
live healthy lives

October 2015

Dear Valued Customer,

Important Update Regarding the Availability of ENFit™ Connectors

Over the past several months, BD has been working closely with the healthcare community to better understand these concerns and to share them with the broader industry. However, due to fundamental differences in the approach to delivering a safe ENFit™ solution that works for all patients groups, BD has withdrawn from the Global Enteral Device Suppliers Association (GEDSA), effective September 19, 2015.

Over the past several months, BD has been working closely with the healthcare community to better understand these concerns and to share them with the broader industry. However, due to fundamental differences in the approach to delivering a safe ENFit™ solution that works for all patients groups, BD has withdrawn from the Global Enteral Device Suppliers Association (GEDSA), effective September 19, 2015.

BD will continue to supply the BD UniVia™ Oral/Enteral syringes to hospitals around the world. The BD UniVia™ Oral/Enteral syringes do not connect to Luer devices and comply with U.S. medical device regulations.

BD will continue to work with the clincal community and the International Organization for Standardization (ISO) to find a data driven solution not only to address the low dose concerns but also to ensure a safe and reliable syringe, while remaining within the upcoming ISO 80369-3 standard.

Please contact your local BD representative should you have questions regarding this matter.

Amardeep Singh Chahal
Sr Business Director, WW Injection Systems

Regina Haywood, RN, MSN, ANP
Associate Director, Medical Affairs

MSS0905-1 10/15

Medtronic

This letter is to provide you with an update on the transition of Medtronic's enteral feeding products to the ISO 80369-3 universal standard. Medtronic has been a member of the trade association formed to assist industry with creating and implementing this standard – the Global Enteral Device Supplier Association (GEDSA) – since its inception in 2013 and we fully support the ENFit™ standard adopted by the overwhelming majority of GEDSA's members.

The clinical community has voiced its concerns regarding the potential impact the current design may have with respect to low dose administration of medication. In response to these issues, GEDSA has identified a solution that it believes will eliminate the risk of improper dosing. The specifications of, and access to the intellectual property rights to, this design have been provided to GEDSA's members. Medtronic is actively working with other GEDSA members and is in communication with the FDA in preparation for this solution.

As you may be aware, Becton, Dickinson, and Company (BD), the largest syringe provider in the U.S., has recently withdrawn its membership from GEDSA over what it says are "fundamental differences in the approach to delivering a safe ENFit™ solution that works for all patients [sic] groups." BD has publicly communicated its concerns regarding the basic ENFit™ connection but it has not publically disclosed to our

Accordingly, for the reasons outlined above, Medtronic, despite having ENFit™ products available in the first calendar quarter of 2016, **will be delaying the launch of our ENFit™ syringes and access devices until syringe manufacturers will be able to produce sufficient quantities of ENFit™ syringes to meet market demand.**

Accordingly, for the reasons outlined above, Medtronic, despite having ENFit™ products available in the first calendar quarter of 2016, **will be delaying the launch of our ENFit™ syringes and access devices until syringe manufacturers will be able to produce sufficient quantities of ENFit™ syringes to meet market demand.**

Medtronic looks forward to taking a leadership role to ensure that patient safety remains the top priority for the industry. The third tenet of Medtronic's Mission is **"To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."** This is a responsibility we take very seriously and one that guides every decision we make with respect to our products. Accordingly, we will continue to monitor these issues and work to address any additional concerns that come to our attention.

Sincerely,

A Gradual Transition Designed to Prevent Disruption

Key dates for US, Canada, Puerto Rico

Q1 2015
Administration Sets with ENFit female connector and ENFit Transition Connector

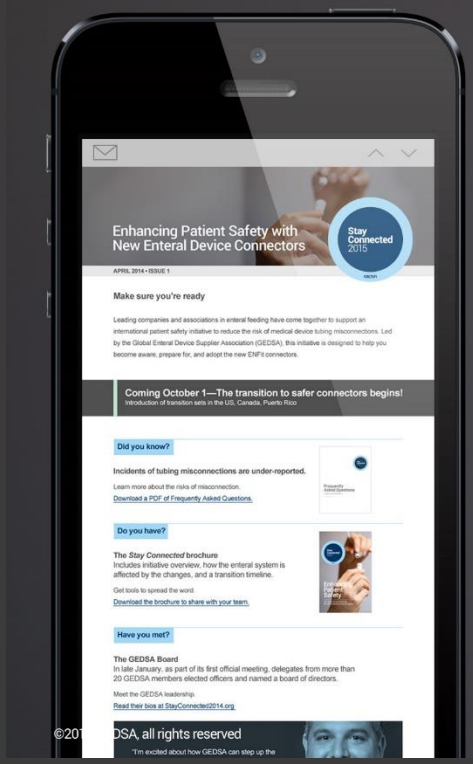
1st Half 2016
Enteral-specific syringes with ENFit female connector

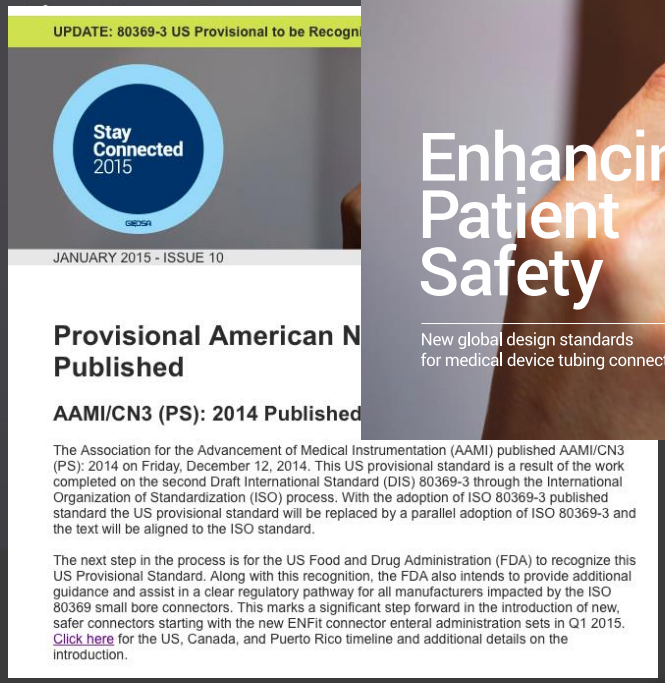
1st Half 2016
Feeding tubes with ENFit male connector

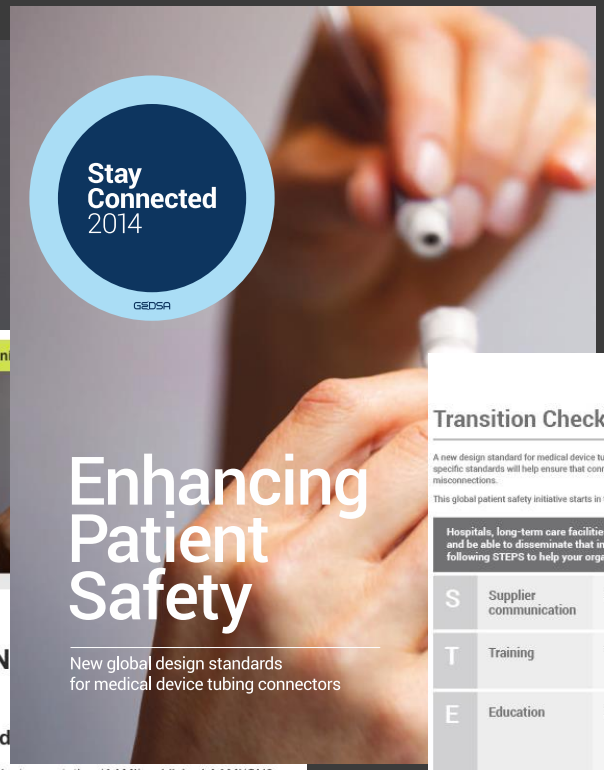
Pending FDA 510(k) clearance

Stay Connected

Brochures, Presentations, FAQs & Checklists at www.stayconnected.org







GEDSA

Stay Connected

Recommendations

- Work with your Enteral Feeding Device Suppliers:
  - Understand their specific ENFit Transition Timing for all enteral tubes and syringes
  - Verify ability to meet your demand
  - Find a back-up Plan
- Syringes:
  - 1 & 3mL Syringes should have a Low Dose Tip (5mL depending on supplier and facility needs)
  - 6mL and above should not have a Low Dose Tip
  - Verify adequate supply to meet facilities demand and home bound patient at discharge prior to ENFit tube placement

QUESTIONS?