Advisor Live®
Transitioning to ENFit Connectors: A Safer Enteral Feeding System

July 14, 2016

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Moderator: Gina Pugliese, RN, MS, Vice President, Premier Safety Institute

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Logistics

Audio

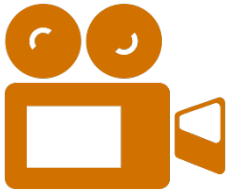
Use your computer speakers or dial in with the number on your screen

Notes

Download today's slides from the event post at premierinc.com/events

Questions

Use the "Questions and Answers" box or Twitter #AdvisorLive



Recording

This webinar is being recorded. View it later today on the event post at premierinc.com/events

Faculty

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WHY YOU SHOULD CARE ABOUT TUBING MISCONNECTIONS

Debora Simmons PhD RN CCNS FAAN
UTHealth

Disclosure

I have no commercial financial relationships to disclose.

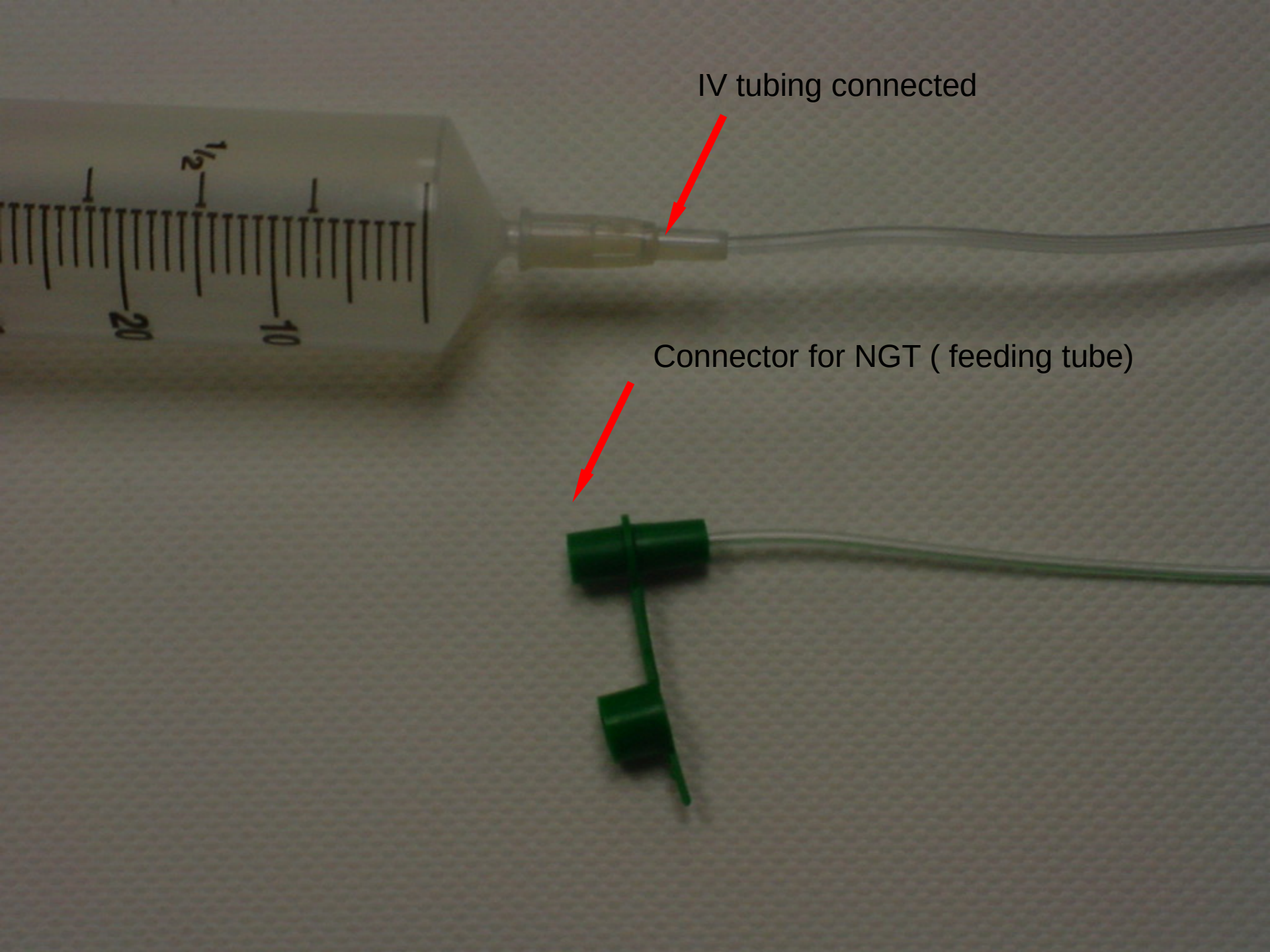
The opinions expressed in this presentation are solely my own.

This presentation is in debt to the work of Bryanne Patail BS, MLS, FACCE (retired NCPS), Peggi Guenter, PhD, RN, CNSN, Scott Coburn MS, RN and Nancy Pratt, MSN, RN, CCRN


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

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


IV tubing connected
Connector for NGT (feeding tube)

Human Factors Science – Safety Science Automatic mode errors

- Are unavoidable
- Happen predictably with repeated acts
- Are failures of actions going as intended
- Occur in common and familiar functions in familiar surroundings
- Are usually not detected by the participant

Reason 1990

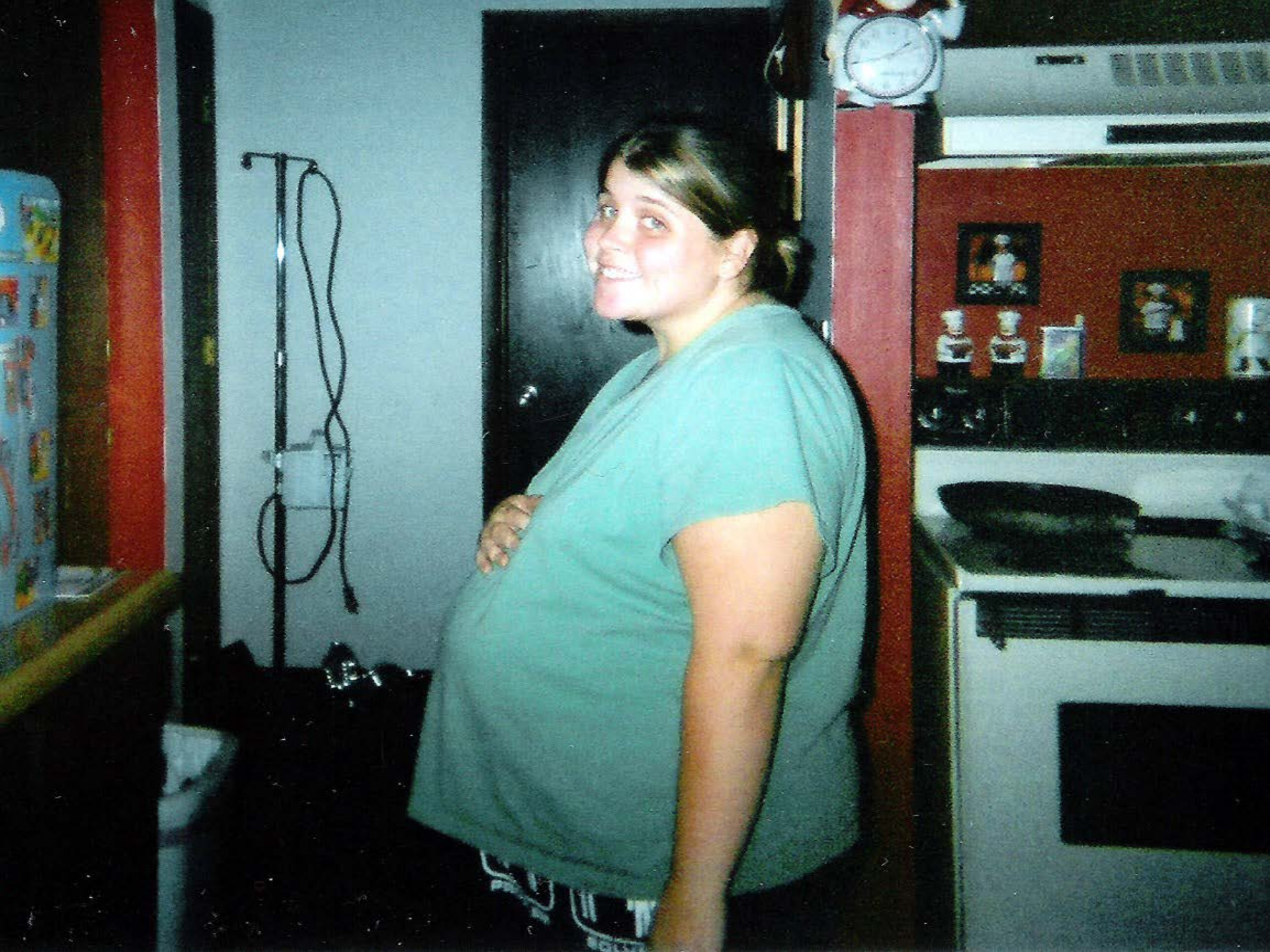
Automatic Mode

- Locking the keys in the car
- Dialing the wrong number
- Putting the milk in the cabinet and cereal in the refrigerator
- Spilling your coffee

Error is Inevitable Because of Human Limitations

Who endorses this change ?
EVERY MAJOR SAFETY ORGANIZATION

- FDA
- AAMI
- ISMP
- ECRI
- American Nurses Association
- Joint Commission
- The American Hospital Association



What has happened in the last ten years to fix this safety hazard ?

- California passed a law after the vincristine intrathecal death of a young man
- California law was postponed because of vendors lobby
- AAMI brought consensus expert groups together nationally and internationally to change the standard across all connectors in coordination with the FDA
- The standards were changed

What has happened in the last ten years to fix this safety hazard ?

- GEDSA began consensus meetings with vendors to coordinate efforts
- BD – the largest manufacturer dropped out of GEDSA and wants to design their own connector delaying implementation for another three to four years
- People are still dying from this error

The Facts

- We know without a doubt this is a safety hazard leading to patient death
- We know it is present in almost every healthcare setting
- We know every major safety organization has supported this change
- There is no reason to tolerate this any longer

Design standards for system-specific applications

Tom Hancock - GEDSA

ENFit®

80369-3

Stay Connected

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

GEDSA

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

vizient

MEDICATION SAFETY COLLABORATIVE

NPSF
National Patient Safety Foundation

The Oley Foundation
Help along the way

PREMIER

A Global Effort to Enhance Patient Safety

Stay Connected

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

Significant Testing Conducted to Verify & Validate Enteral Standard Design

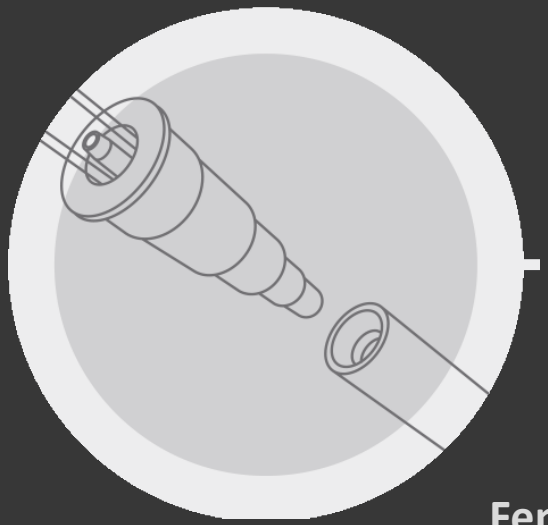
Testing & Assessments

- Clinical Assessment - 20 Physicians, Nurses & Pharmacists
- Usability/Human Factors - 53 Clinicians (including 15 NICU)
- Misconnections Assessment
- Syringe Accuracy Report
- User Survey – 35 respondents in 3 European markets
- Acceptability and Suitability Study - 48 Clinicians in 6 European Markets
- LDT Syringe
  - Performance Testing
  - Usability Testing – 140 respondents in 8 countries
  - Misconnection Risk Assessments
- Reverse orientation usage – UK reverse Luer
  - Millions of patients over nearly 6 years without a reported event

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

CURRENT

Male Stepped or "Christmas Tree" Connector from Administration Set

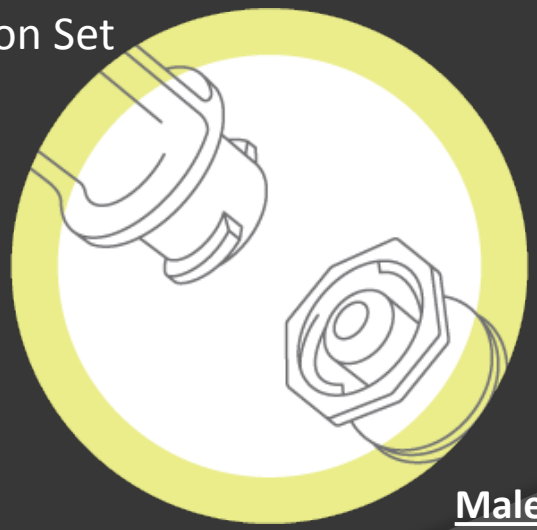


Female Feeding Tube Port

NEW

ENFit

Female ENFit Connector from Administration Set

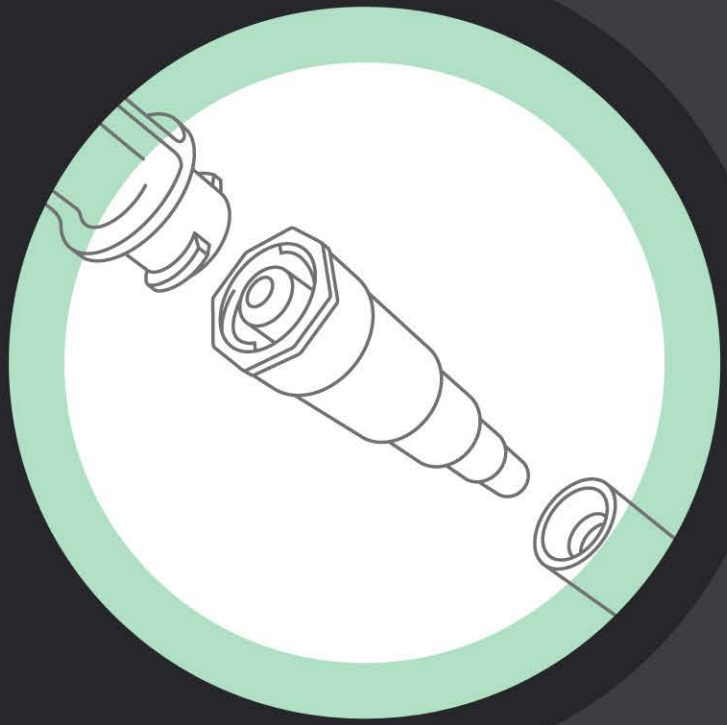


Male ENFit Connector for Feeding Tube

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

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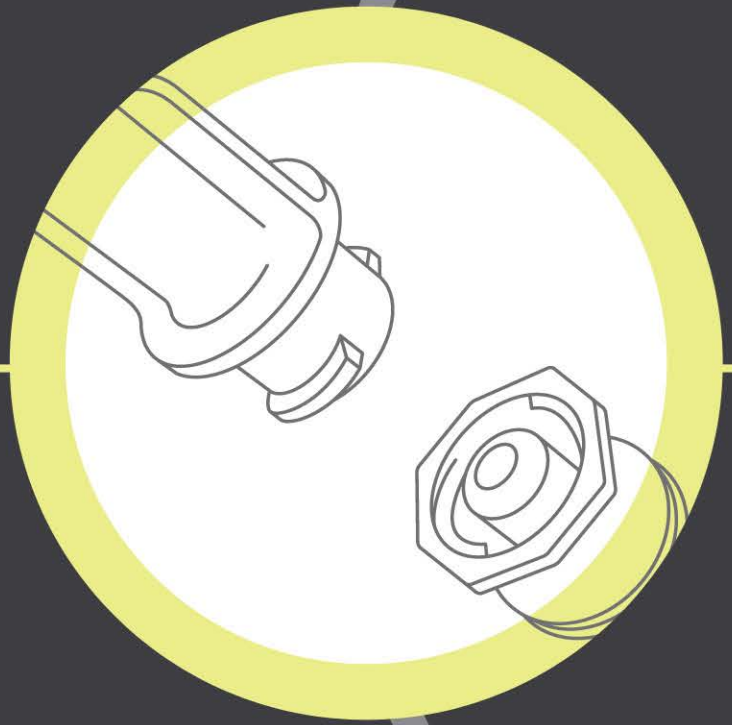
ADMINISTRATION SET

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

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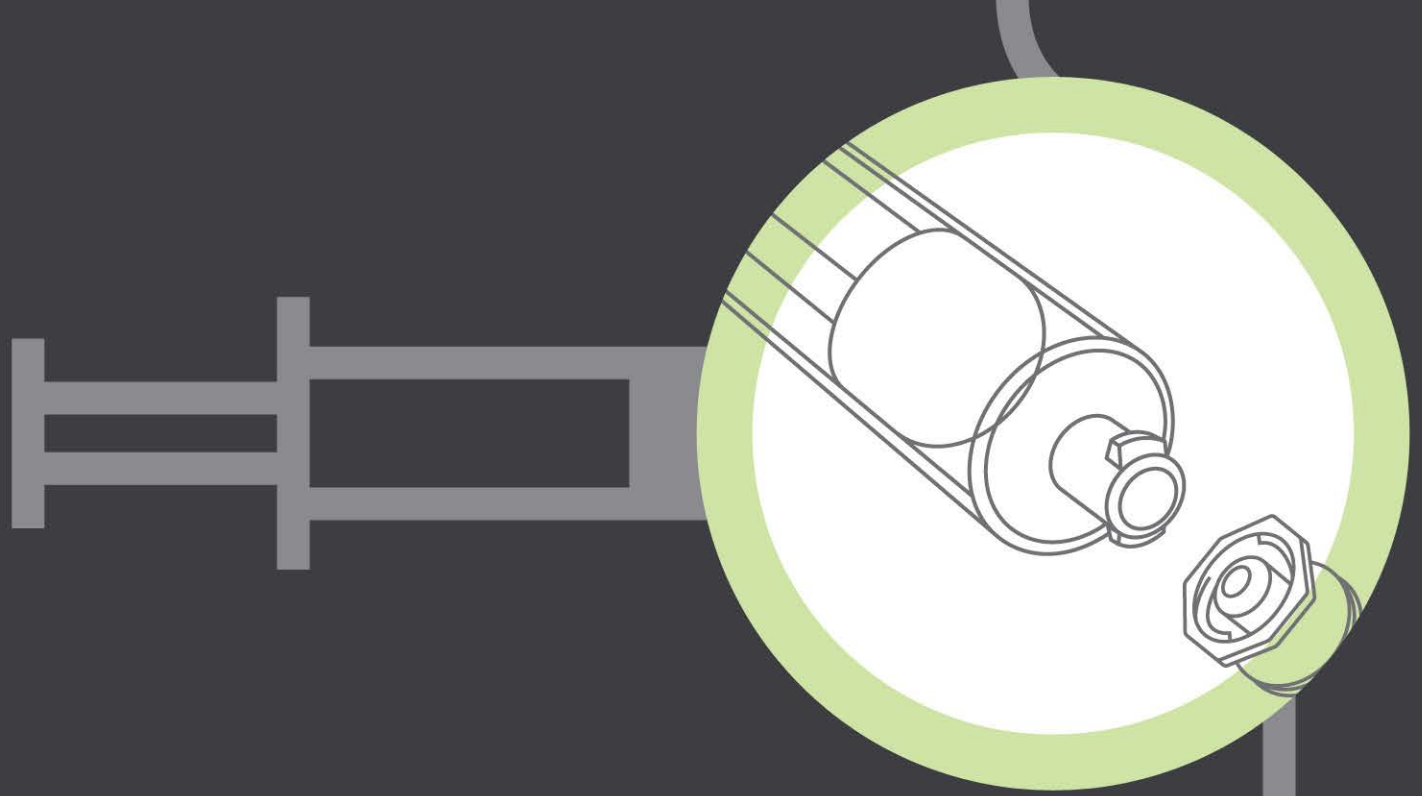

SYRINGES

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

- Administer Medicine
- Flush
- Hydrate
- Bolus Feed

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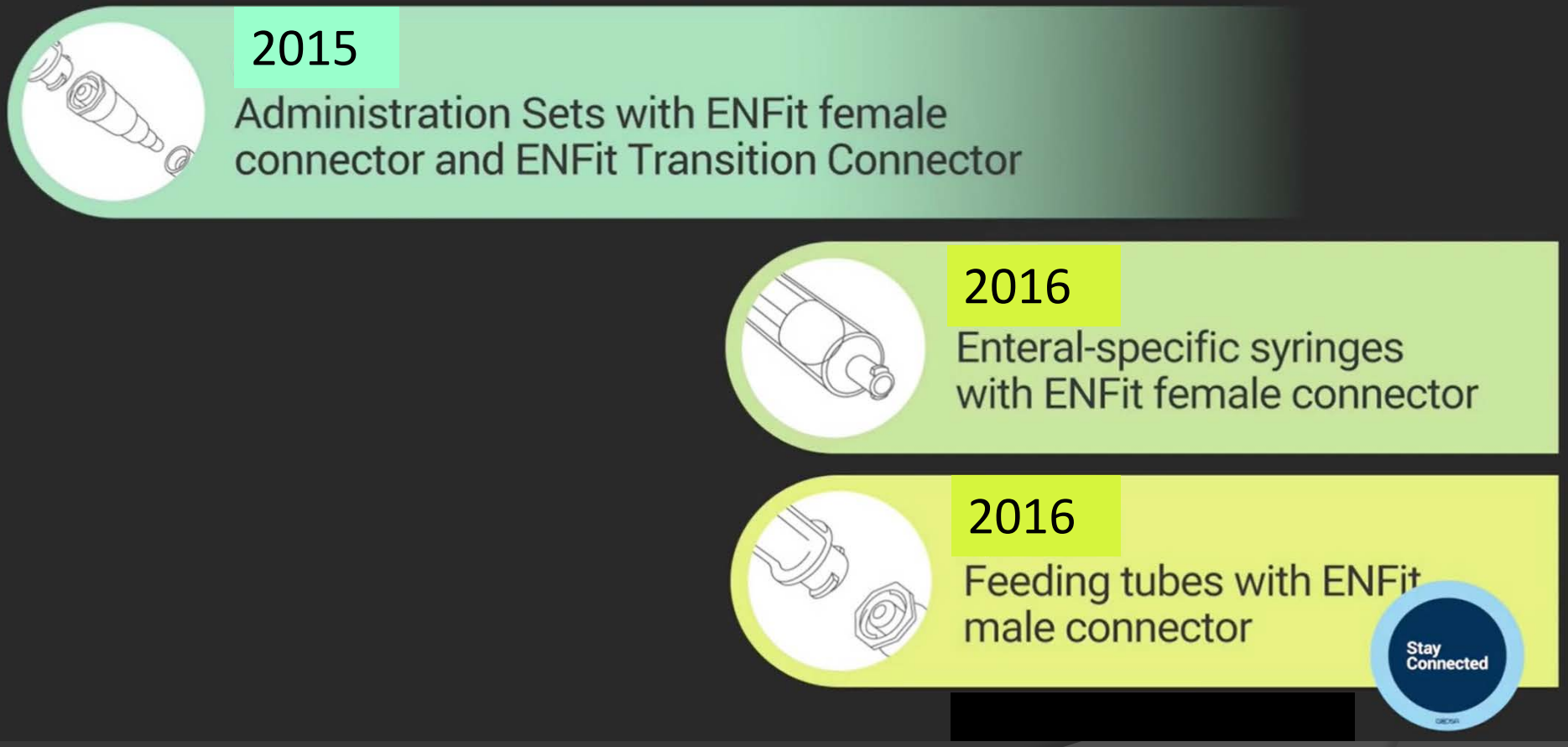
ENFit Transition Timing



- GEDSA Members have confirmed their commitment to ENFit and the introduction of syringes and feeding tubes in 2016

Global Introduction of ENFit – NOW!

North America

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Global Introduction of ENFit

Europe, Middle East, Africa, Australia & New Zealand

Stay Connected

Global Introduction of ENFit - 2017

South America, Asia

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California Legislation

- California Senate Bill No.158: *"Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for…".*
- Assembly Bill 444 delayed the effective date to for hospitals and suppliers to July 1, 2016
- GEDSA, AdvaMed, CHPSO, CHA have been in communication with the state to provide updates on manufacturers progress
- No indications from CA Department of Health as to how and when they will enforce
- Be prepared!

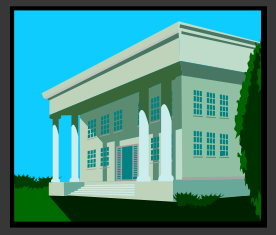
Variations in Enteral Feeding Point of Care that Affect Adoption/Implementation

Acute Care (AC)

Home Care (HC)

Other Countries

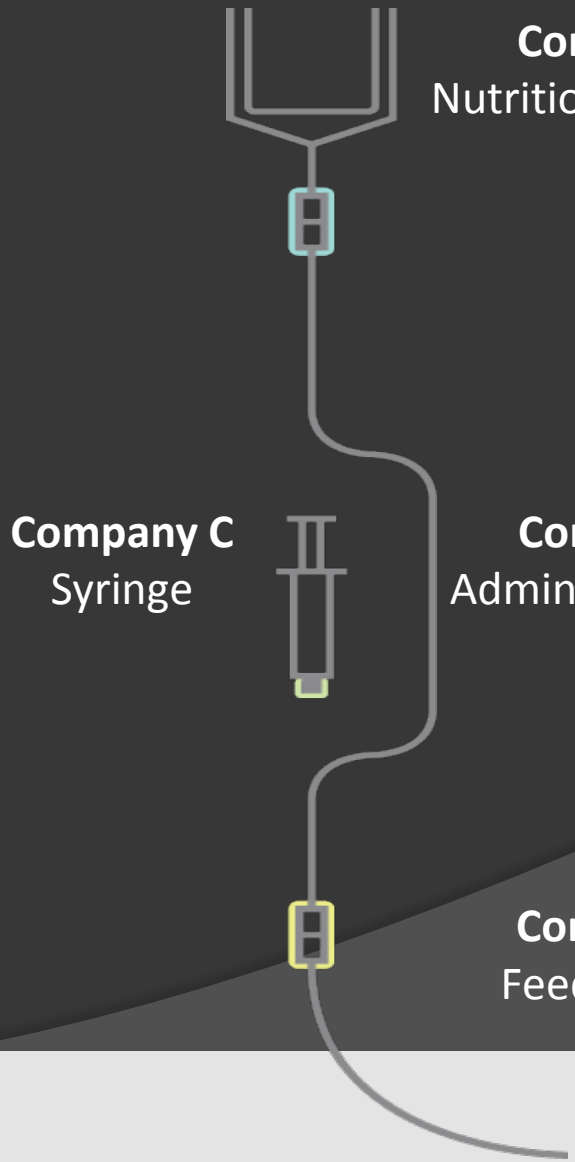
Other States



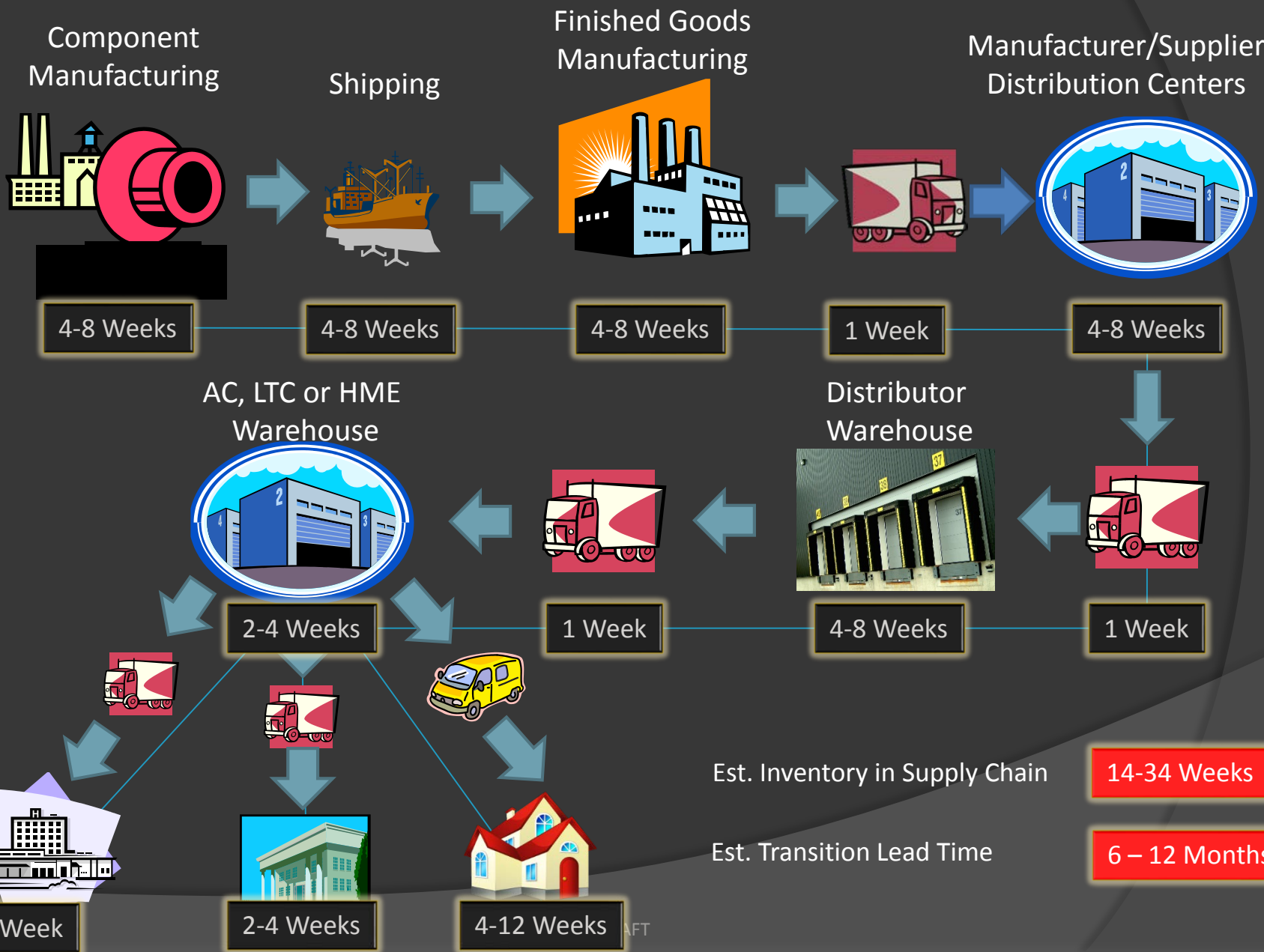
Long Term Care (LTC)

Complications of Supply Chain

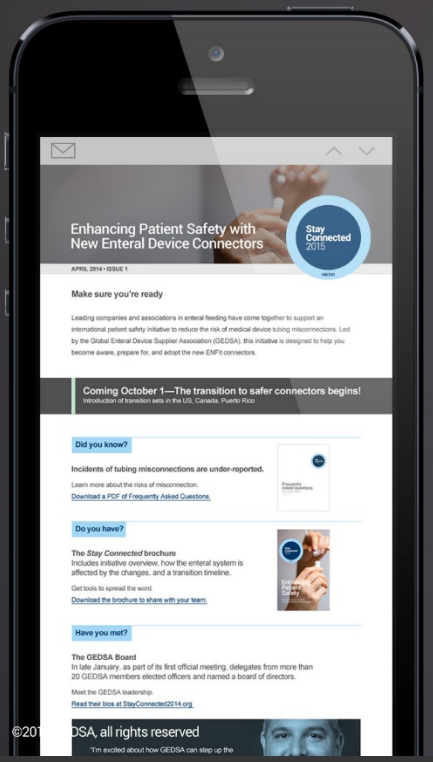
- Inventory Levels
- Connectivity Between Suppliers
- Additional Issues
  - Changing Product Codes
  - Excess and Obsolescence
  - Returns

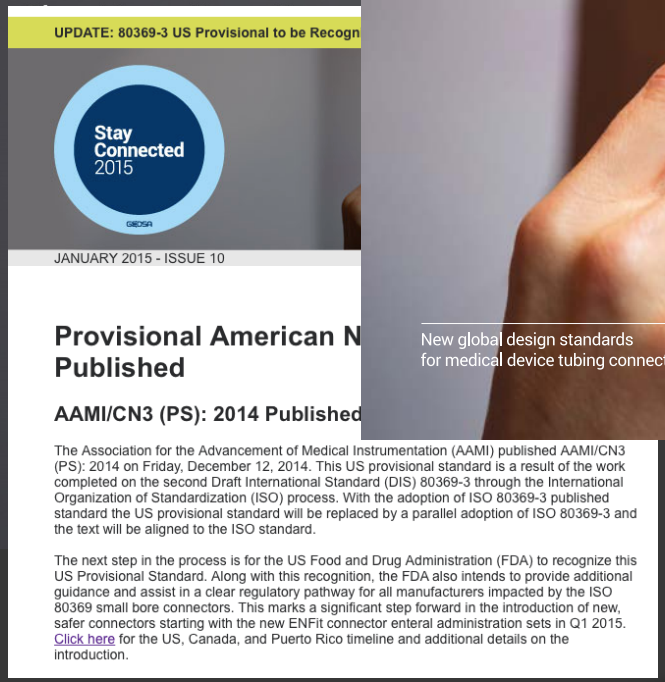


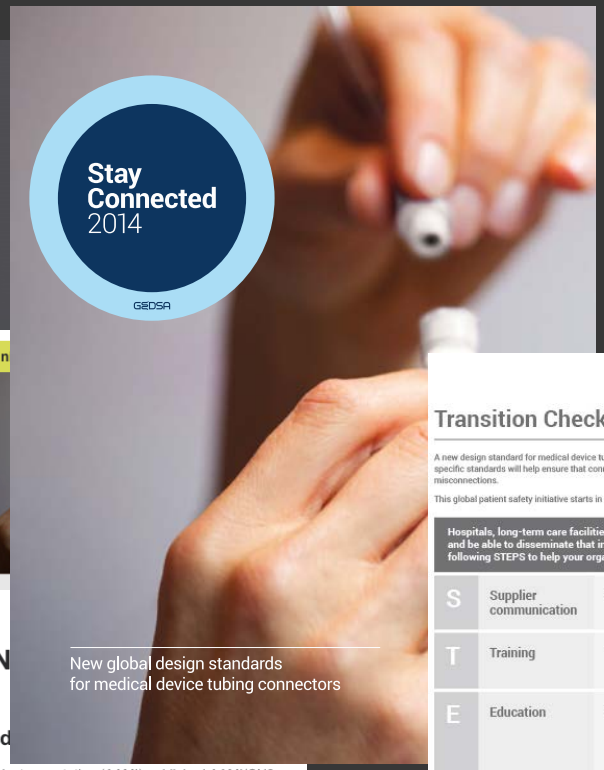
Complexities in Supply



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







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Reporting an Adverse Event

- Reach out to the manufacturer customer service via phone or email.
- Each manufacturer may have a different procedure for handling the complaint but have the same obligation to keep track of and investigate a complaint
- Contact information can be found on the company website
- Common information you will need when you contact the company:
  - Patient age, gender, and medical condition
  - Clear and detailed description of event
  - List of all devices relevant to the event
  - Product identifiers like brand name, model and lot number

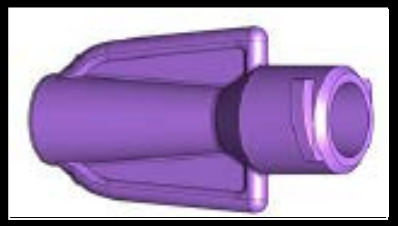
Important Links

- GEDSA
  www.stayconnected.org
- California Legislation
  http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB444
- FDA
  http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
- ISO Standard
  http://www.iso.org/iso/catalogue_detail.htm?csnumber=50731
- Premier Safety Institute
  http://www.premierinc.com/tubingmisconnections

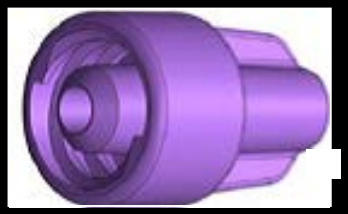
CLINICAL USE OF ENFIT SYRINGES

Mike Cohen
Institute for Safe Medication Practices

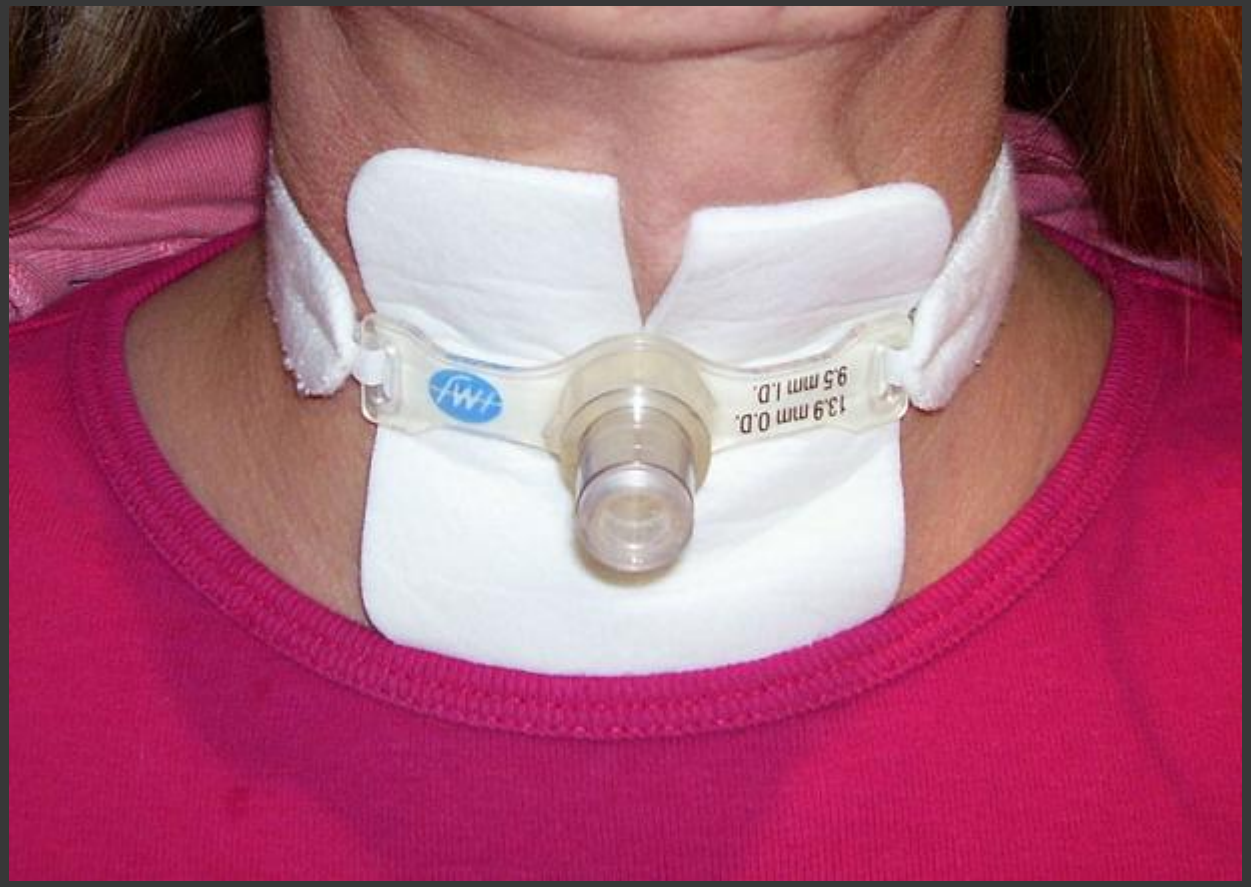
ENFit syringe and tube connectors



New ENFit pump set connector Design (replaces stepped connector) – gender is female



New ENFit feeding port design – gender is male


13.9 mm O.D.
9.5 mm I.D.

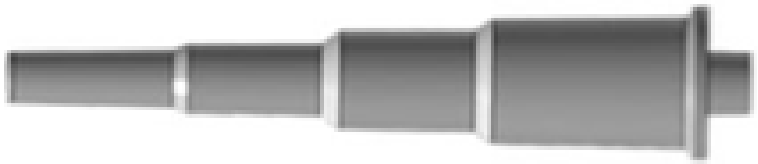
Filling caps for bottles available in various diameters

Pharmacy dispensing

- When preparing liquids using ENFit syringes and devices in pharmacy, volume measured in between arrows.

Pharmacy dispensing

- Some of the other ENFit devices that can be used by pharmacy to prepare liquids with ENFit syringe

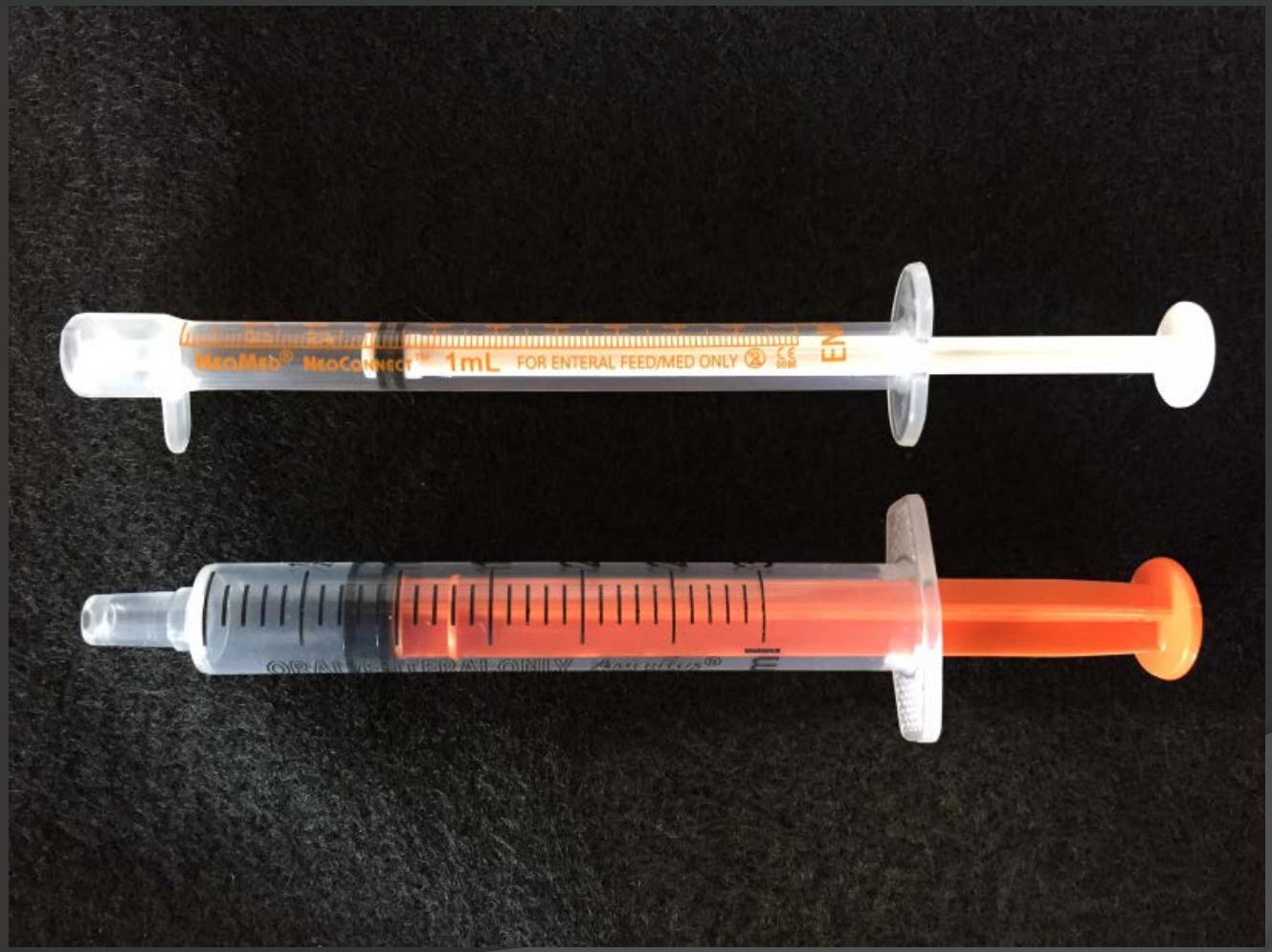


Pharmacy dispensing

- Pharmacy may be able to use a single ENFit syringe whether via enteral feeding tube or oral.
- Some concern expressed for neonatal population due to “flange” on low dose syringes. May need to have two different syringes – one for oral and one for enteral, although difficult to operationalize

1. Communicating which type of syringe is needed
2. Will hospitals maintain one type of syringe only?

ENFit syringe (top) with typical oral syringe



NeoMed DoseMate

Preparing doses from bottles with flow restrictors (usually patients at home)

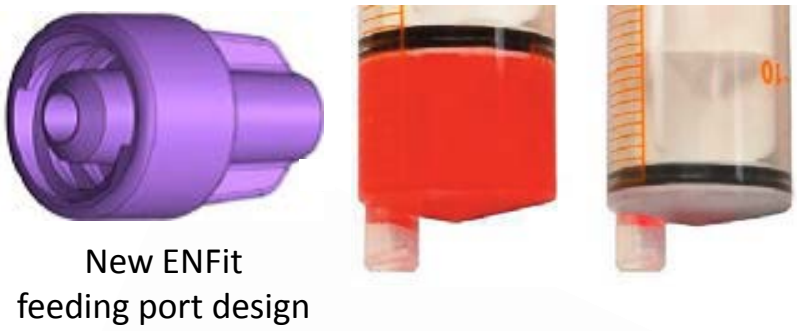
Previous dosing accuracy concerns

- Clinicians raised concerns last year about dosing accuracy of small volume ENFit™ syringes, due to their reverse gender orientation
- There is not a 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
- Clinicians and pharmacists indicated a dosing accuracy of expectation of ± 10% of the target volume
  - Indicated that this dosing accuracy percentage is expected with doses as small as 0.2mL when delivered from a 1mL syringe
- Testing indicates that syringes with maximum volume of 5 mL and below may require a low-dose tip to satisfy the dosing accuracy target

Pharmacy dispensing

- Intention is for liquid contents to be administered via ENFit tubing.

- However, if syringe used orally instead of via an ENFit, some fluid remained in dead space of syringe.
- A concern for small syringes and small liquid doses

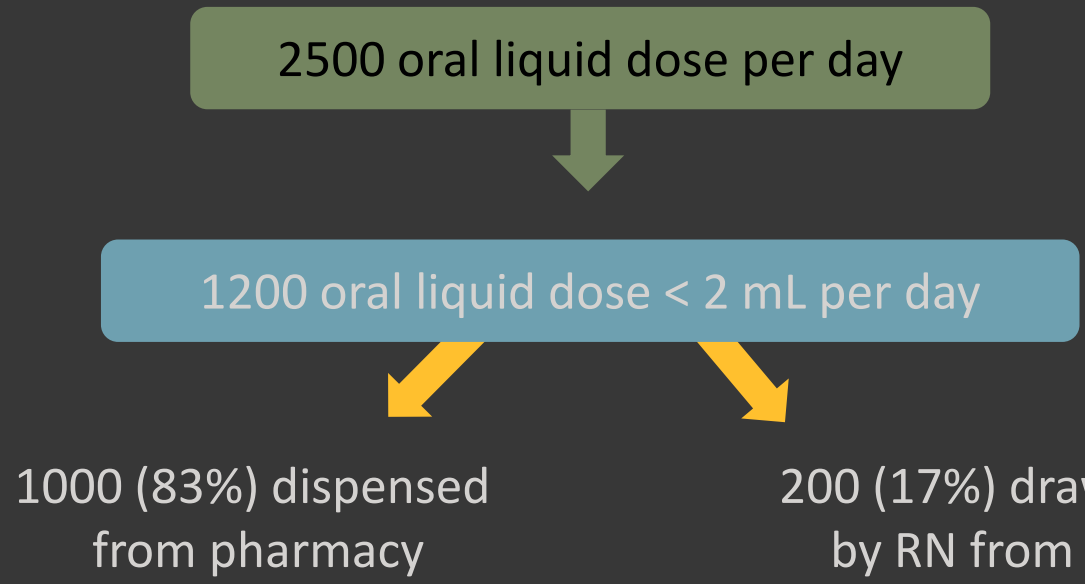


New ENFit feeding port design

Common low dose & some high risk medications

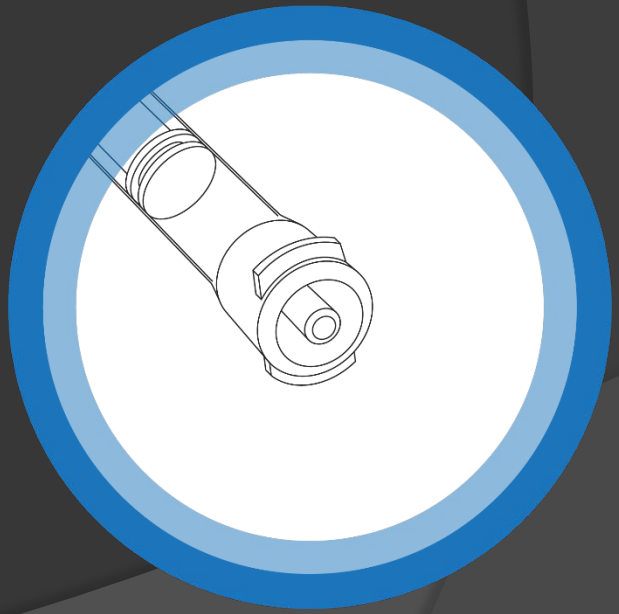
Acetaminophen	Clonidine	Hydralazine	Oxybutynin
Acetazolamide	Clopidogrel	Hydrocortisone	Phenobarbital
Acyclovir	Cyclosporine	Hydromorphone	Phenytoin
Amlodipine	Desmopressin	Hydroxyurea	Phytonadione
Amoxicillin	Dexamethasone	Isradipine	Potassium chloride
Amoxicillin / Clavulanate	Diazepam	Labetalol	Prednisolone
Atenolol	Diazoxide	Lansoprazole	Propranolol
Azithromycin	Digoxin	Levetiracetam	Ranitidine
Baclofen	Docusate	Levothyroxine	Risperidone
Bactrim	Enalapril	Lisinopril	Sildenafil
Bethanechol	Ergocalciferol	Lorazepam	Simethicone
Bumetanide	Etoposide	Midazolam	Sirolimus
Caffeine	Erythromycin	Methadone	Sodium chloride
Calcitriol	Famotidine	Mercaptopurine	Spironolactone
Calcium carbonate	Ferrous sulfate	Metoclopramide	Tacrolimus
Captopril	Flecanide	Metronidazole	Topiramate
Cefdinir	Fluconazole	Morphine	Topotecan
Chlorothiazide	Folic Acid	Nystatin	Ursodiol
Chloecalciferol	Furosemide	Omeprazole	Valganciclovir
Clindamycin	Gabapentin	Oxycodone	Vitamin E
Clonazempan	Glycopyrrolate	Oxcarbazepine	Zidovudine

Data from Children's Hospital in Philadelphia



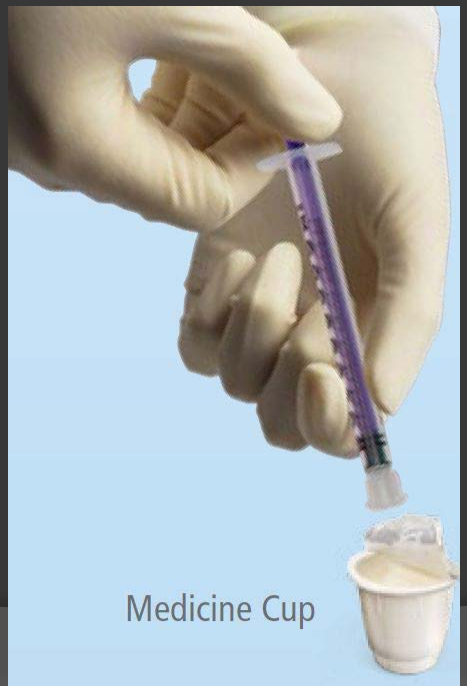
Low dose tip ENFit™ syringe

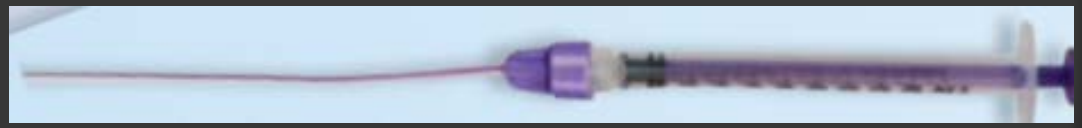
- The ENFit Low Dose Tip (LDT) Syringe was designed to specifically address the dosing accuracy concerns.
- Design proposed for inclusion into ISO 20695 enteral device standards
- LDT is: Standard female syringe tip with an internal tip lumen.
- Mimics functionality of traditional male oral/enteral syringe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

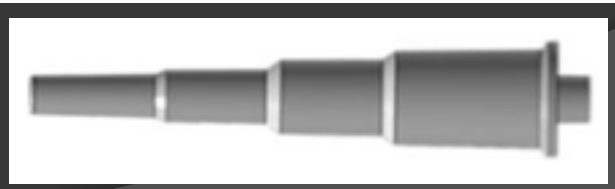


Nurse dose preparation on nursing unit

- Nurses must sometimes prepare oral liquid doses in various patient care areas for oral administration (ED, NICU, Med-Surg, etc.). Unit dose cups are most common. For safety reasons, bottles of liquids holding multiple doses are not dispensed by pharmacy.





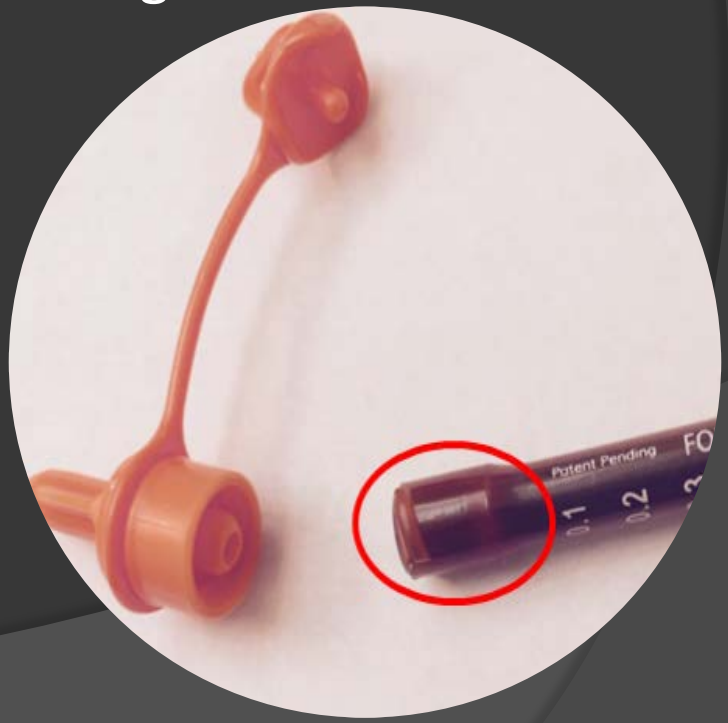


Nurse dose preparation on nursing unit

- Another issue was bubble formation in syringe when ENFit syringe is used but fluid drawn straight from cup, not via an ENFit device as in the pharmacy.
- Air in tip of syringe is drawn into syringe.
- Bubble expelled for accurate measurement
- Low dose syringe addresses these issues

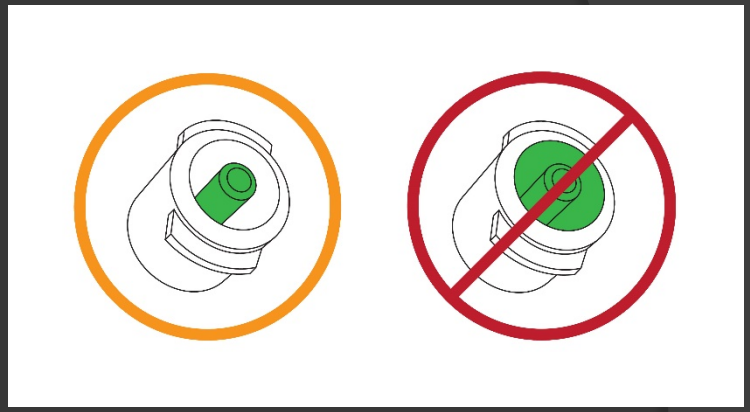
Nurse dose preparation on nursing unit

- When drawing from cup for dose intended for ENFit feeding tube, fluid may not be expelled from ENFit syringe tip after bubble expelled.
- Could result in slight overdose or leakage.



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 that may be outside the fluid pathway.



- Method of filling the syringe (cup fill vs straw/adapter fill)
  - The straw/adapter fill method is more accurate than the cup fill method because there is less potential for excess residual fluid on the syringe to transfer to the feeding tube.
- Orientation of the syringe and/or feeding tube during filling and disconnection
  - Depending on orientation during disconnection after filling, excess fluid may flow toward the syringe creating residual fluid on the syringe that can transfer to the feeding tube.
  - Depending on orientation during disconnection from the feeding tube after dispensing, excess fluid may flow into the feeding tube or fluid may flow back out of feeding tube.

Dosing accuracy summary

Syringe Type	Expected Lower Bound (Under-Dosing %)	Expected Upper Bound (Over-Dosing %)
Standard 1mL ENFit™ Syringe (A)	-24.06%	28.15%
E/O (Male Tip) 1mL Syringes (B,C,D)	-7.37%	9.69%
Reverse Orientation 1mL Syringe (E)	-11.20%	18.00%
Reverse Orientation 1mL Syringe (F)	-3.96%	21.22%
1mL LDT ENFit™ (LDT1)	-2.90%	10.47%

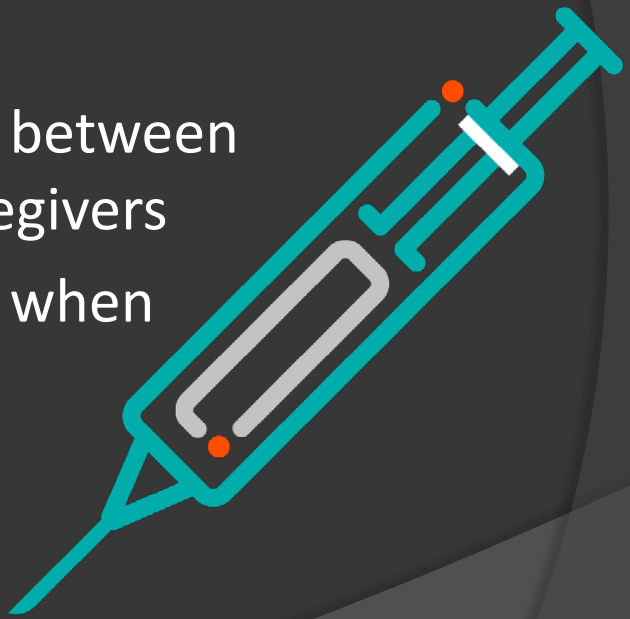
- Key Takeaways:
  - Dosing accuracy performance of the 1mL Low Dose Tip ENFit™ syringe is similar to the currently marketed Enteral/Oral (Male Tip) Syringes
  - The Low Dose Tip outperforms currently marketed Reverse Orientation Syringes

GEDSA ENFit usability study participants information

	Pharmacist	Nurse	Caregiver	Total
ASHP (ASHP)	20	0	0	20
Nationwide Children's Hospital (Columbus, OH) (NCH)	0	14	0	14
Children's Hospital of Philadelphia (CHOP)	1	14	1	16
Fairview Health Services (Minneapolis) (FHS)	0	8	3	11
Children's Hospital of Atlanta (CHOA)	2	2	0	4
Pediatric Home Services (Minneapolis) (PHS)	0	0	5	5
Children's Hospital Colorado (CHC)	2	10	0	12
Johns Hopkins (Baltimore) (TJHH)	4	10	0	14
United Kingdom	0	10	0	10
Ireland	0	5	1	6
Australia	0	9	0	9
New Zealand	0	19	0	19
Totals	**29**	**101**	**10**	**140**

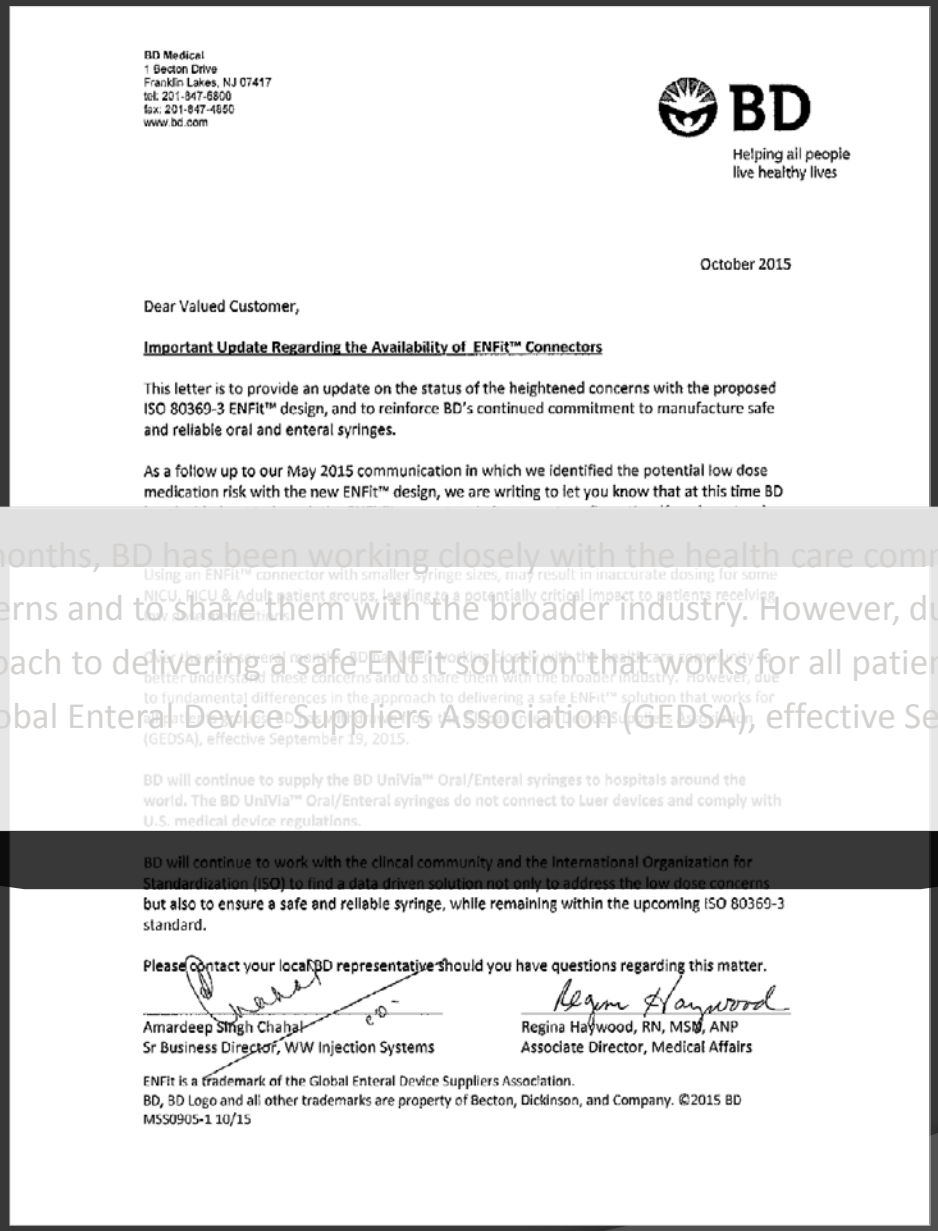
Usability testing top level summary

- No significant differences for syringe use when filling or administering water or a thicker liquid (Pepto-Bismol)
- 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



Low dose ENFit™ syringe conclusion

- Performance Test Results (when used as instructed):
  - Dose Acccuracy 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) and standard ENFit™ (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 provides a solution for accurate enteral dosing while maintaining a high level of mitigation to 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*



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BD
Helping all people live healthy lives

October 2015

Dear Valued Customer,

Important Update Regarding the Availability of ENFit™ Connectors

This letter is to provide an update on the status of the heightened concerns with the proposed ISO 80369-3 ENFit™ design, and to reinforce BD's continued commitment to manufacture safe and reliable oral and enteral syringes.

As a follow up to our May 2015 communication in which we identified the potential low dose medication risk with the new ENFit™ design, we are writing to let you know that at this time BD

Over the past several months, BD has been working closely with the health care 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 patient groups, BD has withdrawn from the Global Enteral Device Suppliers Association (GEDSA), effective Sept. 19, 2015.

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

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MSS0905-1 10/15

QUESTIONS?

Venting

Questions:

- How will people vent with an ENFit connector?
- People are concerned that they will not be able to vent through the G portion of a G-J tube. Is that a legitimate concern?

Answers:

- Device specific performance Issue.
- Most common G-J tubes inner diameters will not change and therefore performance will not be negatively impacted

Cleaning

Question:

How will consumers keep ENFit connectors clean?

Answers:

- A reverse system with a very similar design has been in place in the United Kingdom resolved by proper tube maintenance and flushing.
- When flushing with a syringe, keep final 0.5 inch (centimeter) of the tubing or syringe free of formula.
- There are already products being promoted for the cleaning of the ENFit connectors.
- ASPEN will be issuing guidance on proper cleaning techniques including the use of household swabs (ie. Q-Tips)

Clogging

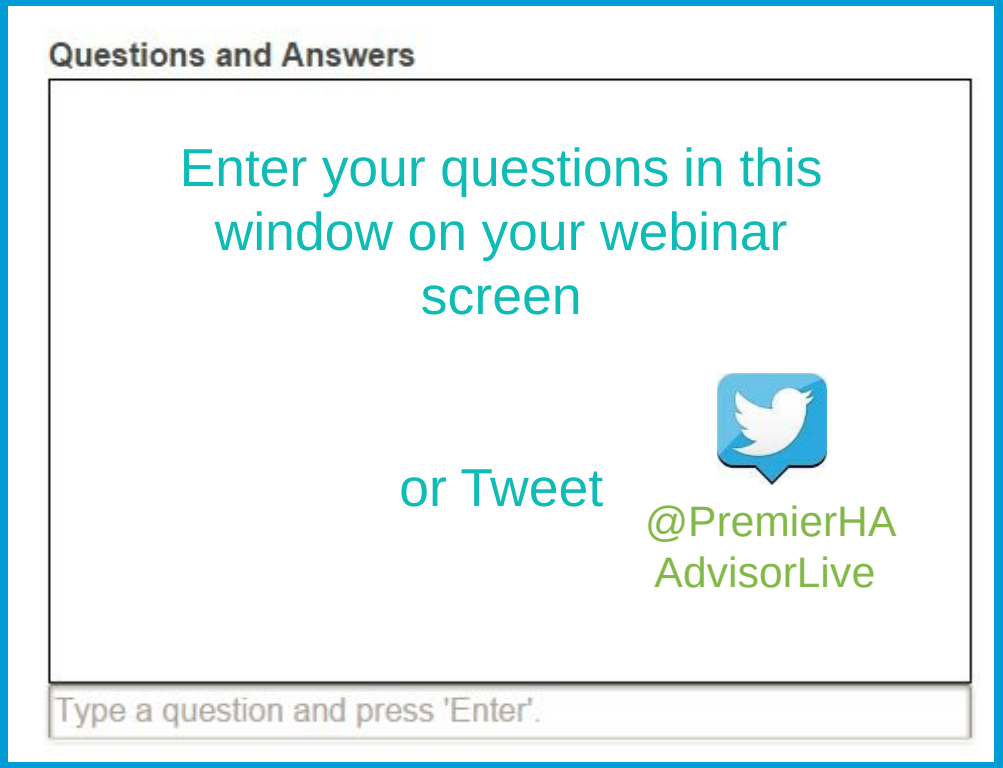
Question:

- Clogging is always a big problem with feeding tubes. Do you anticipate more clogging with a smaller-bore connector?
- Many are concerned that their tubes will need to be replaced more often, either because a clog or tube gets dislodged (pulled out) accidentally.

Answers:

- Clogging would be a device specific performance attribute.
- ISO Requirements specify a forcing function and prefer a locking feature
- The risk inadvertent disconnections, a common complaint from tube fed patients and caregivers, will be lower with the ENFit system due to the interlocking design.

Your questions



Thank you for joining us!

For more information, contact:

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Want to find out more about today's topic? Answer the poll question here now.

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