



Small Connectors, Big Impact:

Understanding ISO 80369

Presenter

- › Presenter's Name: Rikki Lynn Doyle, RPhT
- › I have no current or past relationships with any commercial entities





Presentation Structure

- › What is ISO 80369?
- › A Short History of the Luer
- › Describe Tubing Misconnections
- › ISO 80369 and Patient Safety
- › ISO 80369 standard series: The 8 parts
- › Adoption of ISO 80369
- › Discussion Questions
- › Q&A



Learning Objectives

- › 1. To explain the purpose and scope of ISO 80369
- › 2. To review how compliance with ISO 80369 can improve patient safety
- › 3. To assess global adoption and conversion to ISO 80369 compliant devices



What is ISO 80369?

- › International Organization for Standardization
- › 80369 is a series of medical device standards that cover small bore connectors for direct individual patient care
- › The standards were developed to improve patient safety

ISO 80369-1

- General Requirements and Overview

ISO 80369-2

- Breathing Systems and Driving Gases
- Airway

ISO 80369-3

- Enteral and Gastric
- Stomach
- **ENFit**

ISO 80369-4

- Urinary Collection
- Urethra

ISO 80369-5

- Limb Cuff Inflation
- Tourniquets and BP Cuffs

ISO 80369-6

- Neuraxial
- Spine

ISO 80369-7

- Intravenous
- Arteries and Veins
- **The Luer**

Short History of the Luer



Image from: Brown, J The Life and Death of the Luer, MD&DI Online

- Hermann Wulfing-Lüer first manufactured the luer syringe in 1894, 130 years ago
- Invented by Karl Schneider....???? Or Jeanne Luer
- The simple design went on to be an effective connector for a wide variety of medical applications
- In 1925 Fairleigh S. Dickinson filed a US patent for a modification that would come to be known as the LUER-LOK





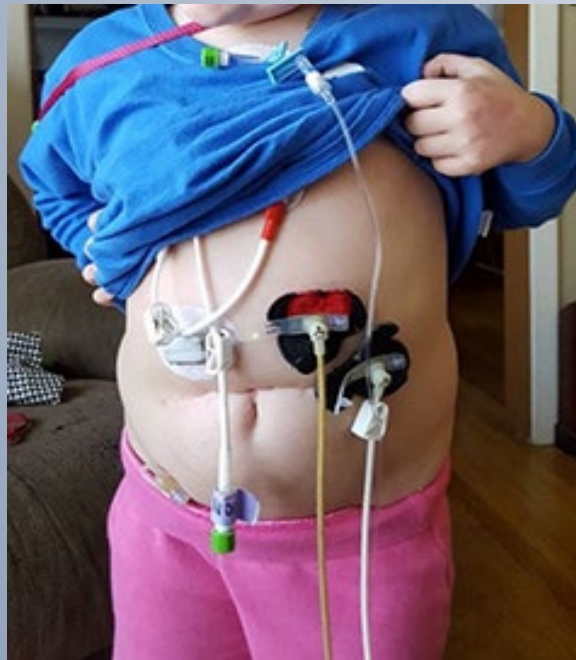
[Looking Back: Ramstein air show crash > Office of Special Investigations > Display \(af.mil\)](#)



Prefilled syringes - Prefilled syringe automated inspection & end-product testing - Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/figure/Photograph-of-Luer-lock-tip-and-cap_fig2_324546890 [accessed 19 Feb, 2024]

What is a tubing misconnection?

- › *“Tubing, catheter and syringes are a fundamental aspect of daily health provision for the delivery of medications and fluids to patients. The design of these devices is such that it is possible to inadvertently connect the wrong syringes and tubing and then deliver medication or fluids through an unintended and therefore wrong route. This is due to the multiple devices used for different routes of administration being able to connect to each other”*





In Their Own Words Two

Examples of Medical Device Misconnections | FDA

- › An anesthetist and a mid wife mistakenly connected an epidural set to a patient's IV tubing as a result epidural medicine was delivered to the IV causing patient death.
- › A child in a pediatric ICU had both an IV line and a trach tube. The IV tubing was mistakenly connected to the trach cuff port. The IV fluid over-expanded the trach cuff to the point of breaking and continuous IV fluids entered the child's lungs resulting in the child death.
- › A patient was found with her Foley catheter disconnected from its drainage bag. One end of the catheter was still in her bladder and the other end was connected to her nasogastric (NG) tube. Urine was noted to be flowing into her NG tube. The NG tube was connected to suction and more than 300 mL of urine drained. The patient's vital signs were stable, and her laboratory results were within normal limits



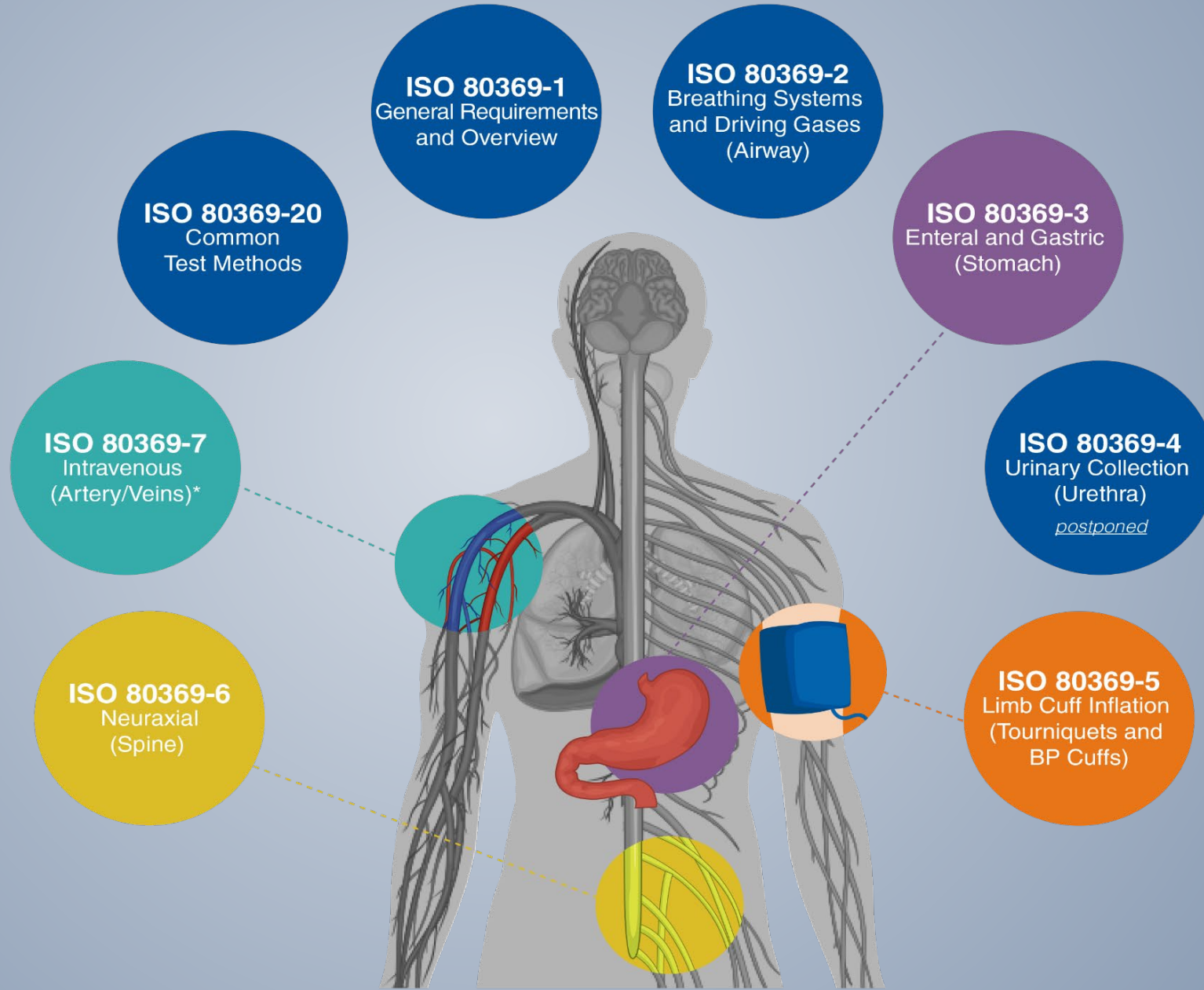


FIGURE 2

Comparison of Syringe Tips⁶

ENFit syringes less than 5 mL were redesigned with a low-dose tip and paired with new dispensing adaptors, like transfer straws, to increase dosing accuracy and avoid inadvertent overdosing due to drug accumulation in the “moat” at the syringe tip.



Image courtesy of the Global Enteral Device Supplier Association (GEDSA) (<http://stayconnected.org/wp-content/uploads/2019/03/GEDSA-White-Paper-2019.pdf>.)





HIERARCHY OF EFFECTIVENESS

SYSTEM-BASED

High Leverage

MOST EFFECTIVE

Forcing functions and constraints

(e.g., removal of a product from use)

Automation or computerization

(e.g., automated patient-specific dispensing)

Medium Leverage

MODERATELY EFFECTIVE

Simplification and standardization

(e.g., standardized paper or electronic order sets)

Low Leverage

LEAST EFFECTIVE

Rules and policies

(e.g., policies to prohibit borrowing doses from other areas)

Education and information

(e.g., education sessions on high-alert medications)

Reminders, checklists, double checks

(e.g., independent double checks for high-alert medications)

PERSON-BASED



ISMP Canada (2013)



In 2023 Alberta Health Services took the initiative to transition over and meet the global standard changing our supply of enteral feeding products and accessories to be ENfit compliant!



ENFit GLOBAL ADOPTION STATUS

Europe Leads Global Adoption of ISO 80369-3 connectors

North America

- US: ~65%
- Canada: ~50%

Europe

- Nearly 100%

Asia

- ~5% adoption



South America

- ~15%

Eastern Europe, Middle East, & Africa

- ~30% adoption

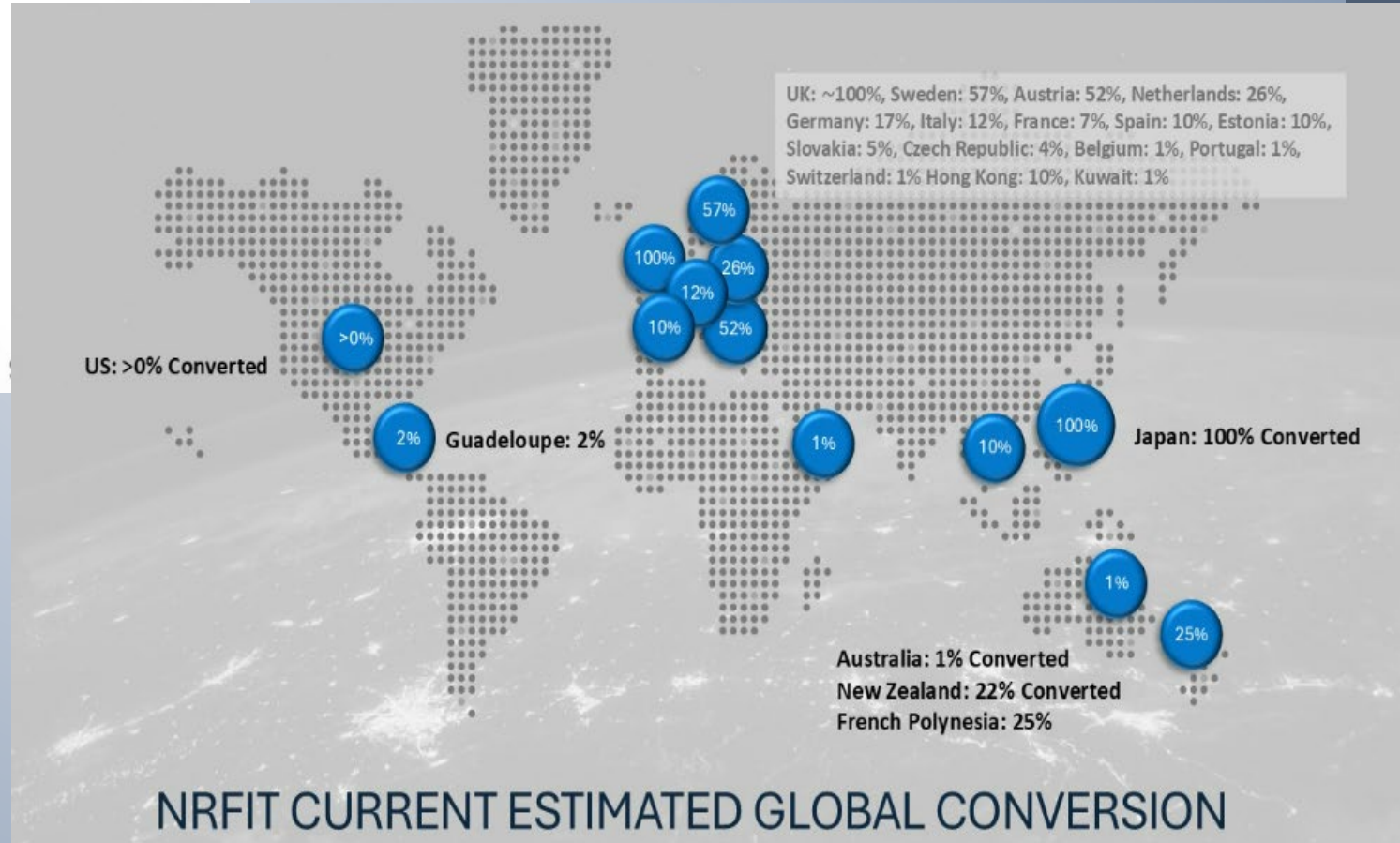
Australia/NZ

- ~80% adoption

Acute care adoption rates are rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world

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Global ENFit and NRFit adoption maps posted stayconnected.org by GEDSA



[ENFit Global Conversion Updates & Map – Stay Connected® by GEDSA™](#)

[NRFit Global Conversion Plans & Map – Stay Connected® by GEDSA™](#)





Discussion Time!



Is there anyone here today whose organization transitioned to ENFit connectors, and were you aware of the purpose behind the transition?



Has anyone here ever been made aware of a medication being administered via the wrong route, either in your own practice or within your organization?



How many adverse events could be prevented if every connector in your facility followed ISO 80369 standards?



Statistics:

A 2024 ISMP article: Survey Results Reveal Tubing Misconnections Are Common and Underreported – Part 1

“A 2010 literature review found 116 cases of *enteral* tubing misconnections, resulting in 21 patient deaths (18%).”

“An article published in 2024 describes 96 new cases of enteral misconnections that have occurred since the previous literature review.”

“During a 20-year review period (between 1999 and 2019), the literature reported 133 cases of neuraxial misconnections. Almost one-third of the events involved practitioners administering epidural medications into IV lines (29%), or IV medications into epidural lines (28%)...26 of the events resulted in patient death”



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Questions?

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