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Are you breaking the law?

An Enfit Journey

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Objectives

- ✓Understand AB 1867 and what it means to CA Hospitals
- ✓Understand the safety concerns related to patients
- ✓Understand the planning process required for a successful transition
- ✓Understand the challenges faced during transition
- ✓Understand the supply chain's role in transition

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What is a Tubing Misconnection?

What is a Tubing Misconnection?

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Also referred to as Luer misconnections, small bore misconnection, wrong route error

An inadvertent connection of tubing from the medical device for one delivery system to a system that **serves a completely different function**

A serious adverse patient safety event resulting in harm & possible death

What is a Small Bore Connector (SBC)?

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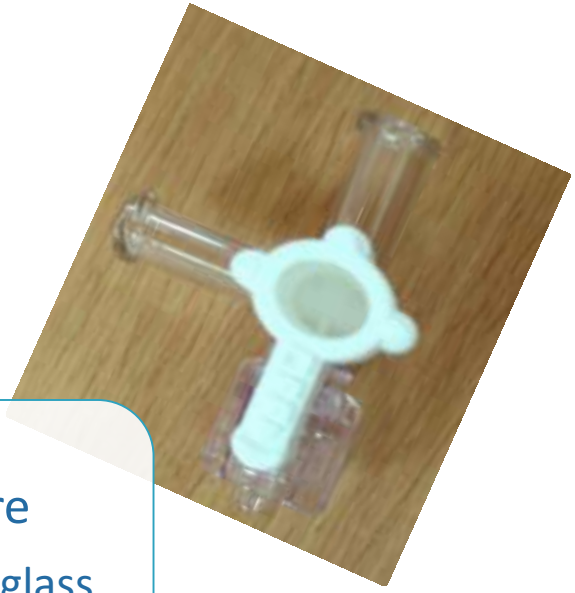
Small-bore Connector: used to link or join medical devices, components, and accessories for the purpose of delivering fluids or gases.



Luer Connector: classic type of a small-bore connector which is commonly used in healthcare

- Designed in 1896 to attach hypodermic needles to glass syringes and are now commonly used worldwide.
- A male and female component are joined to form a secure yet detachable leak-proof connection.
- International Organization for Standardization (ISO) - 595

Universal connector

How Do Tubing Misconnections Happen?

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A typical ICU patient may have as many as **40 connectors**

- Beaumont PICU identified 165 connectors in inventory

Making tubing connections is **a common, routine task**

- Clinicians may make up to 400 connections per day

Clinicians are humans - **humans make errors**

- Distractions, fatigue, poor lighting
- Recurrently & predictably - Especially when in 'automatic mode'

Universal connectors allow misconnections between unrelated systems

- Compatible tubing between unlike systems

How Do Tubing Misconnections Happen?

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Impact of Tubing Misconnections

"When we got to the hospital, we were advised that Chloe's G-tube line had been mistakenly attached to her IV line, causing my fortified breast milk to be delivered to her bloodstream. She was put on life support, suffered DIC, seizures and has various other medical problems, including documented neurological damage. It was the worst day of our lives."

"My heart breaks daily, as I will never know her true potential…sadly, it was taken away from her that day. I don't want what happened to our daughter to happen to anyone; it is totally preventable."

Johannah Back
Chloe's Mother

"We were informed by the surgeon and anesthesiologist in the case that the PACU RN at the surgery center hooked the BP monitor to my mother's IV which caused the air embolus that killed her. I have been a RN for 30 years, worked Floor/CVICU/PACU, etc. and have never heard of such a thing."

"I now feel a need to work tirelessly to educate others and work to eradicate such errors so another family does not have to suffer this incredible pain – I must do this for my mother."

Tricia Otstot, RN
Daughter

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

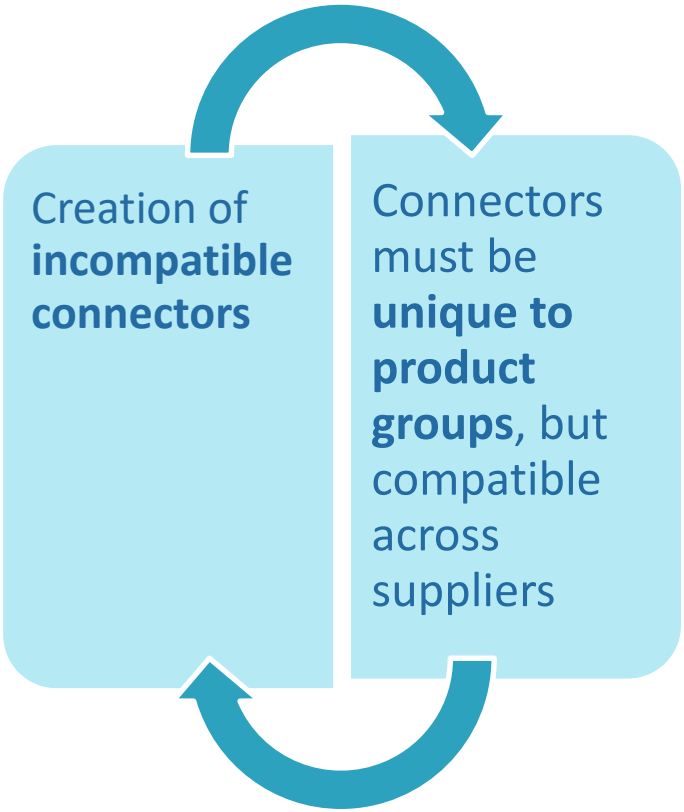
Peggi Guenter, RN, PhD – ASPEN

Prevention requires making wrong connections impossible

- Changing design, shape, or size of the tubing connections

Reducing risk but not preventing

- Review practices and assess risk
- Staff and patient education
- Labeling and color coding



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Time for Change
New Legislation

California Legislation Enacted in 2009

- California AB 1867
  - An act to amend Section 1279.7 of the Health and Safety Code, relating to health facilities
- Enacted in 2009 with effective date of January, 2011
  - Effective dates extended 3X
  - Current effective date **July 1, 2016**
- Prohibits hospitals and skilled nursing facilities from using an epidural, intravenous or enteral feeding connector that fits into a connection port other than the type for which it was intended
  - Requires **UNIQUE CONNECTORS**

- California legislature—2015–16 regular session
- **ASSEMBLY BILL No. 444**

- **Introduced by Assembly Member Gipson**
- (Coauthor: Senator Pan)
- February 23, 2015

- An act to amend Section 1279.7 of the Health and Safety Code, relating to health facilities.

- AB 444, as introduced, Gipson. Health facilities: epidural connectors.
- Existing law, as of January 1, 2017, prohibits a health facility, as defined, from using an epidural connector that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care. Existing law also requires a health facility to develop a patient safety plan and, as of January 1, 2017, requires that plan to include measures to prevent adverse events associated with misconnecting epidural lines. Violation of these provisions is a misdemeanor.

- **This bill would make these provisions operative as of January 1, 2017.**

We aren't done yet……..

ISO Standard	Description
ISO 80369-1	•General requirements for small bore connectors, which convey liquids or gases in healthcare applications. •Misconnection test methods
ISO 80369-2	Breathing systems and driving gases
ISO 80369-3	Enteral and gastric
ISO 80369-4	Urethral and urinary
ISO 80369-5	Limb cuff inflation
ISO 80369-6	Neuraxial devices
ISO 80369-7	Intravascular (IV) or hypodermic (traditional luer with additional dimensional specifications)

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Time for Change
New Products – New Challenges

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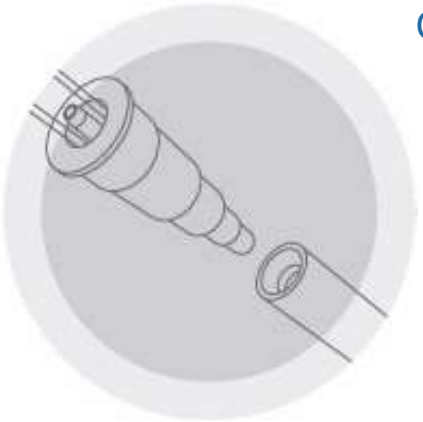
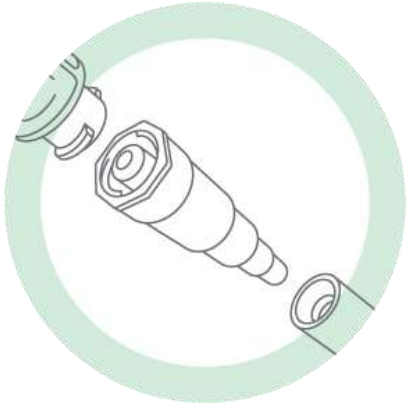
Former

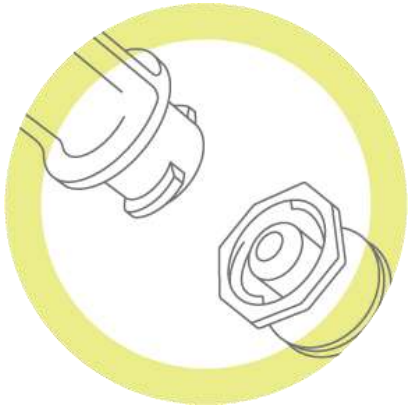


Female ENFit Connector from Administration Set

Transition Connector - Temporary



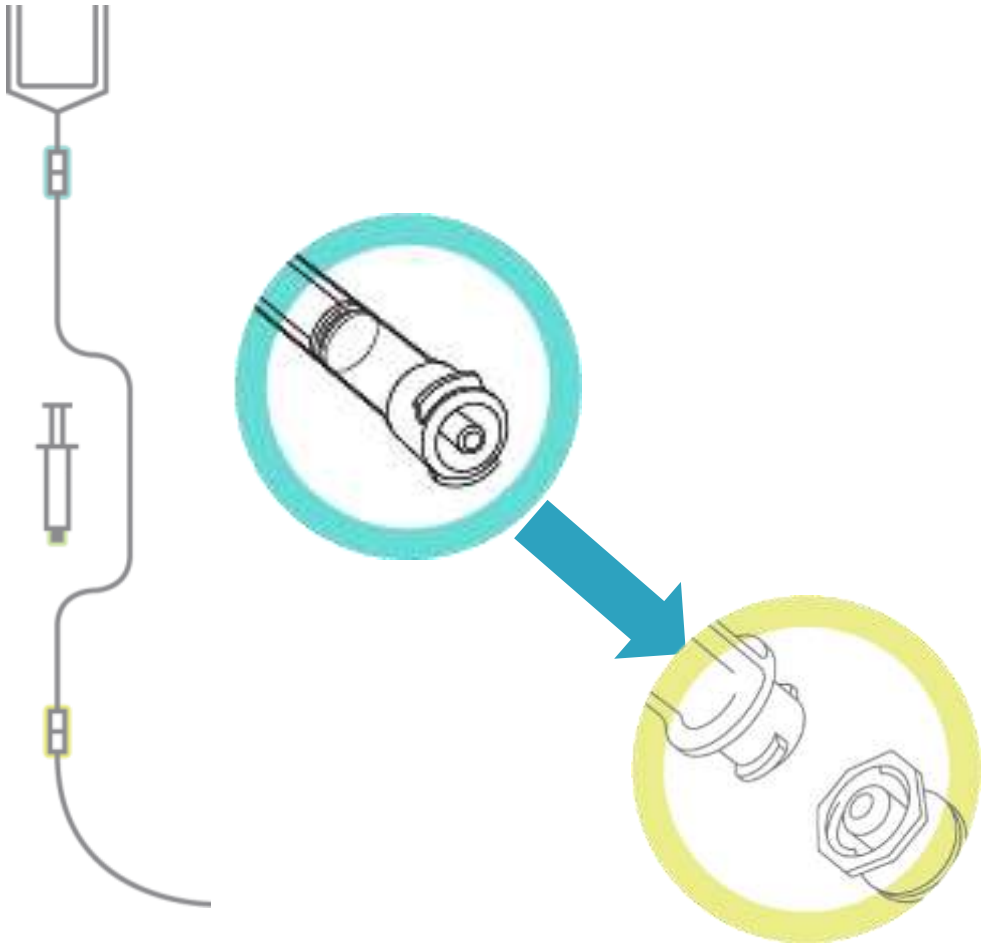
Current



- Syringes used through a feeding tube for:
  - Administering medicine,
  - Flushing
  - Supplemental hydration
  - Bolus feeding
- Require enteral specific syringe with ENFit female connector
  - Oral, Luer or cath-tip syringe will no longer fit into feeding tube
  - Oral, Luer and cath-tip syringes will continue to be available for other uses
  - Available **now**

Products Impacted by the 80369- 3 Standard

A. Administration Sets
B. ENFit® tip Syringe
C. Feeding Tubes
D. Pharmacy/Accessories



Supply Readiness

- Largest Syringe Supplier publicly backed out of ENFit
- Time for other suppliers to ramp up & gain clearance
- Dose Accuracy & Other Concerns
- Ancillary Items
- Perception…

- All of this caused stagnation/loss of momentum

Low Dose ENFit Syringe Conclusion:

Performance Test Results *(when used as instructed)***:**

- 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:

ENFit®, including the Low Dose Tip, mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit

Usability:

No significant difference between use of ENFit® LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)

Solving the ENFit Tip Syringe Access Issues

Rx to Overt the Counter (OTC)

- Requires FDA clearance for each companies set of devices
- Establish Instructions for Use (IFU) for average user
- Usability studies demonstrating IFU can be followed without supervision of a physician

Timing (Anticipate 6-12 Months)

- Usability Testing
- FDA Review and Manufacturer 510k pre-market clearance (TBD)
- Manufacturing and product availability (check with supplier rep)

Manufacturer Challenges

- Cost
- FDA Approvals
- Production – Phased Approach
- Product Validation
- Education and In-Servicing
- Inventory (customer and distribution)
- Different Timelines
- Conversion/Implementation Plan
- Color Adoption
- Understanding the Law – Existing Proprietary Connections
- Syringe Supply Shortage
- Low Dose Syringe – Address Dead Space
- New Product Creation – Address Gaps in Portfolios
- Market Buy-In

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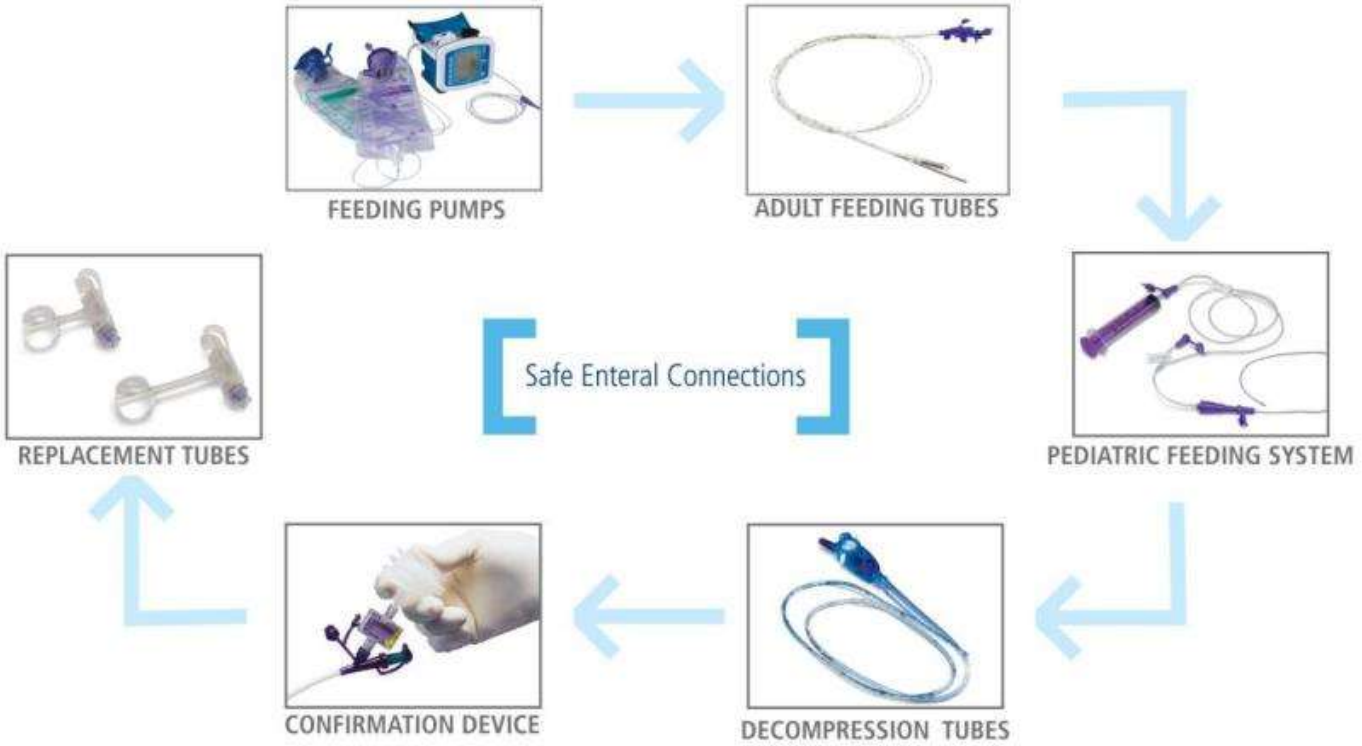
One Connection for All Enteral Feeding



Where ENFit Started

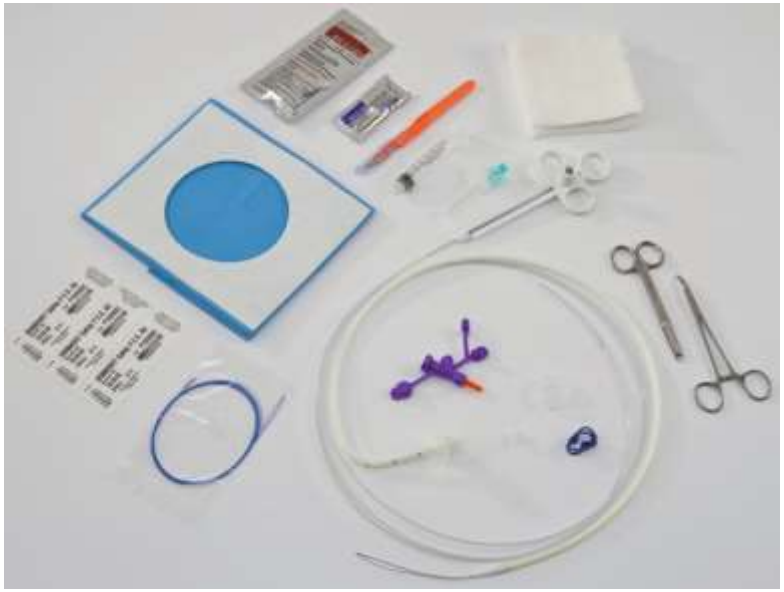
- Nutrition – Spike Sets, Bags, Color Purple
- Adopted by a Majority of Formula and Disposable/Capital Vendors
- Currently Accepted as the European Color For Nutritional Delivery
- Widely Accepted in U.S.A. as New Standard Color

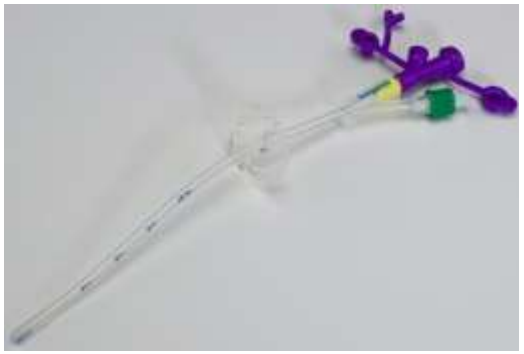
What Does ENFit Look Like

- Adult and Pediatric feeding Tubes and Extension Sets

What Does ENFit Look Like

- G Tubes and PEG Tubes and Skin Level Tubes





What Does ENFit Look Like

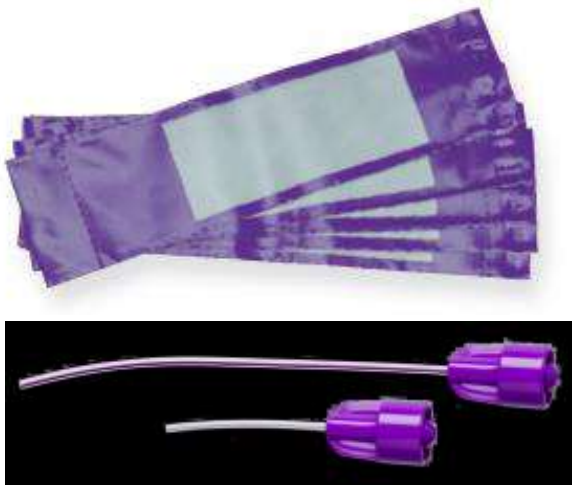
- Enteral Syringes and Accessories

What Does ENFit Look Like

- Irrigation Syringe

What Does ENFit Look Like

- Pharmacy and Solutions



What Does ENFit Look Like

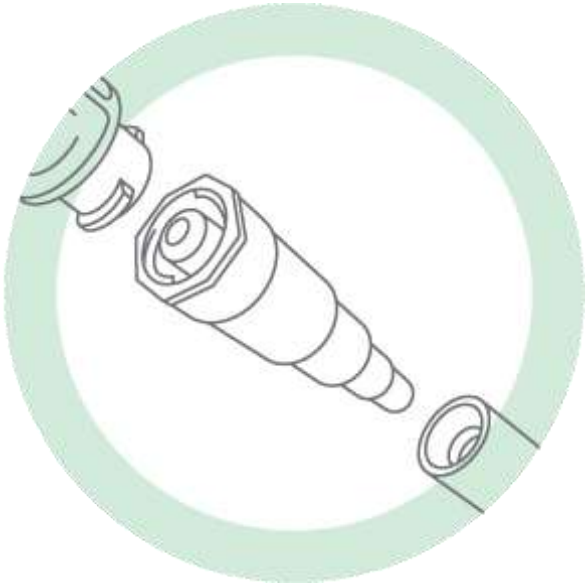
- Syringe Pumps and Gravity Feeding

What Does ENFit Look Like

- Salem Sumps and Multi Function Ports

ENFit Transition Accessories

ENFit Transition Connector



ENFit Funnel Connector

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Time for Change
We've Converted!

Before you Begin: Awareness and Education

- **Organizational Support**
- **Develop Teams**
- **Identify Team Champion(s)**
  - Risk Management
  - NICU/Nursing
  - Products Standards
  - Dietician
  - Physicians
  - Case Managers
  - Pharmacy
  - Supply Chain/Materials
  - Supplier Partner(s)
  - Home Care and Outpatient Care Representative

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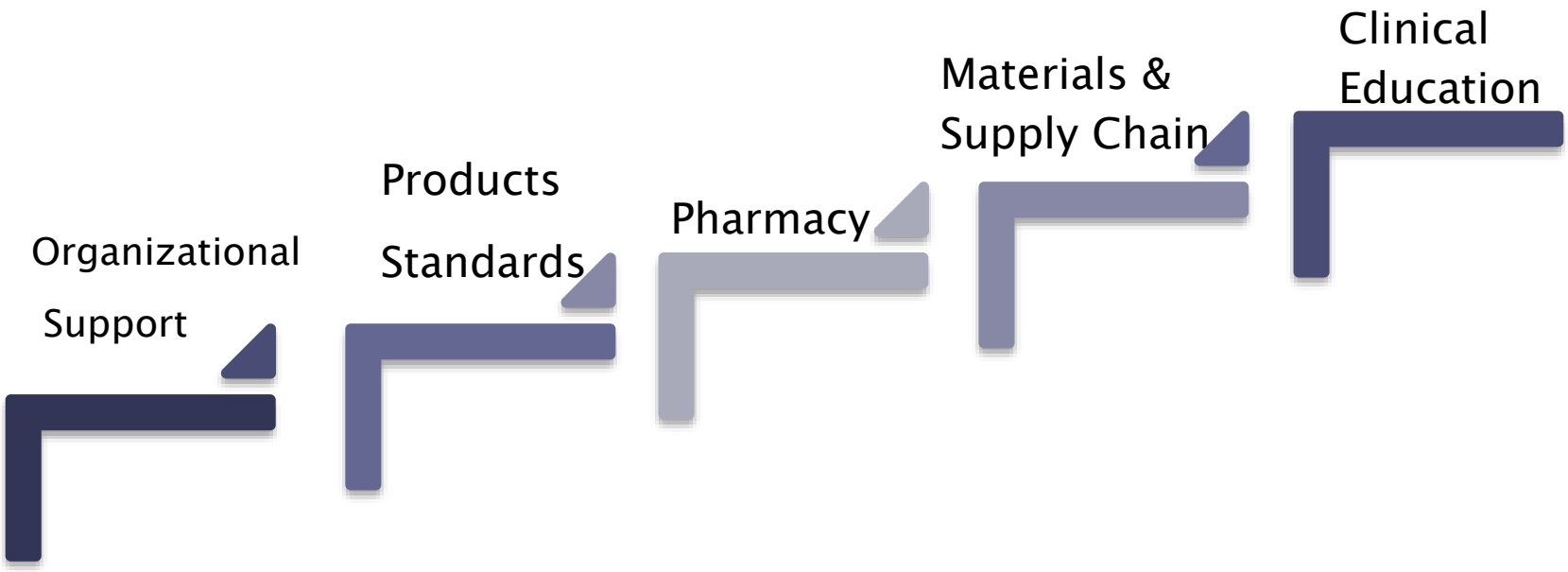

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Challenges

- Time-3 years and counting. When do we go live?
- Approval process-Levels of approval.
- Product availability-who has the product available?
- Obsolete inventory-what to do with obsolete inventory?

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Questions?