THE LIAM CHALLENGE

July 17, 2018
Designing an Innovative Solution to a Problem facing Academic Medicine
OUR TEAM

- Luz Fernandez, Department of Family Medicine
- Farid Kehdy, Department of General Surgery
- Hugh Shoff, Department of Emergency Medicine
- Laura Workman, Departments of Internal Medicine and Pediatrics
DEFINING THE PROBLEM

The inspiration, the background, and why we (and you) should care
Since 2011 prescription pain killers became harder to get and more expensive
- One 80mg Oxycontin pill can run $60-100 dollars
- One dose of heroin is about $9

Overdose Deaths have risen every year since 2011

Opioid related hospitalizations were 2.5% higher in 2016 than 2012

Warren, Beth. Overdose deaths are out of control. Louisville is battling back with this massive plan. Louisville. Courier Journal, Published March 16, 2018
ULH has increasing numbers of hospitalized patients for treatment of infections related to IV drug use
- Multiple Infectious Sites affected
- Many require long-term IV antibiotic regimens
- Identifying a discharge plan can be challenging for these patients
  - Safety concerns related to placement of PICC line
  - Not candidates for typical rehab facilities, home health services
  - Patient compliance with daily infusion centers
U of L data
- Med/Surg  $7,571
- PCU  $7,062

2013 Virginia Commonwealth study
- Partnered with Residential Addiction Treatment Facility to administer the prolonged IV antibiotic therapy were able to save 2.43 million in a 6 year period by reducing length of hospital stay

U of L has one such recent partnership with Centerstone
- Not enough places at Centerstone

doi: 10.1097/ADM.0b013e318294b1eb
A Unifying Problem

- Affects Patients
- Affects Our Community
- Affects our Learning Environment
- Affects our Hospital
CONCEPT AND INITIAL SOLUTIONS

How do we fix the problem?
What are we trying to prevent?

- Patients using their PICC lines for IV abuse outside the hospital
How do we prevent access outside the hospital?

- New Access For Each Infusion?
  - Difficult Sticks
  - Procedures
  - Infection

- Lock and Key Mechanism?

- Disposable PICC Caps?

- IV Tubing Compatible Only With Patient PICC
Collaboration: Department of Biomedical Engineering

- Dr Guru Giridharan, Professor
- Multiple meetings/ ideas discussed
- CAD drawing generated
- Prototypes generated using the 3-D printer
- Office of technology transfer (OTT)
- Provisional patent file #
Three Concepts

Fig. 1 Design 1

Fig. 2 Design 1

Concept Number 1
Three Concepts

Concept Number 2

Fig.3 Design 2 Exploded view

- CAP
- Locking lip
- Zipping surface along luer lock thread
- PICC terminal
Three Concepts

Concept Number 3
What makes this solution innovative

- There are no products on the market which are tamper resistant, only tamper evident
Steri-Tamp® IV Seals

The Only Tamper-Evident Seal that Provides a 100% Sterile Barrier!

Ideal for USP <797> USP <800>
TampAlerT IV Syringe Cap (100 Caps)

Sterile closures for IV syringes!
- Tamper-Evident Luer Lock Closures
- Sterile / Non-Toxic / Non-Pyrogenic
- Utilizes
  - Innovative Zip-tie technology in luer lock design
  - Reusable, unlockable design
What makes this solution innovative

- Multiple iterations put forward, multiple design options
Future designs can be built off of this design

- Peripherally inserted central venous catheter (PICC), or central venous catheters (CVLs) with tamper resistant tubing
- Tamper resistant IV bags, catheters etc.
Feasibility

- Cheap
- Reproducible
- Built on current available platforms
Next Steps

- Create company: start up costs vary
  - Would work with University Marketing and Legal Departments
  - Determine market interest
  - Explore funding sources: Grants, Medical Equipment companies

- Goal: Sell patent to established industry and gain from royalties
Barriers

- Financial:
  - Feasibility study
  - Proof of concept
  - Manufacturing
- Limited interest in this product
  - Other tamper evident products already exist
  - Development of appropriate IM antibiotic formulations that may negate need for this product
  - Unattractive concept?
- Litigation Fears:
  - Broken caps leading to ED visits
  - Patient may still bypass the cap and inject in other sites (other veins, IV bag)
Summary

- Tamper resistant cap to prevent access to PICC line for inappropriate IV drug administration
- Patent pending on prototype
- Market testing
- Decreased length of stays for target patient population, saving healthcare dollars
- Prestige for the University