

IVPlacedit

Problem to Solve

Determine accuracy of placement of peripheral intravenous catheters (PIV).

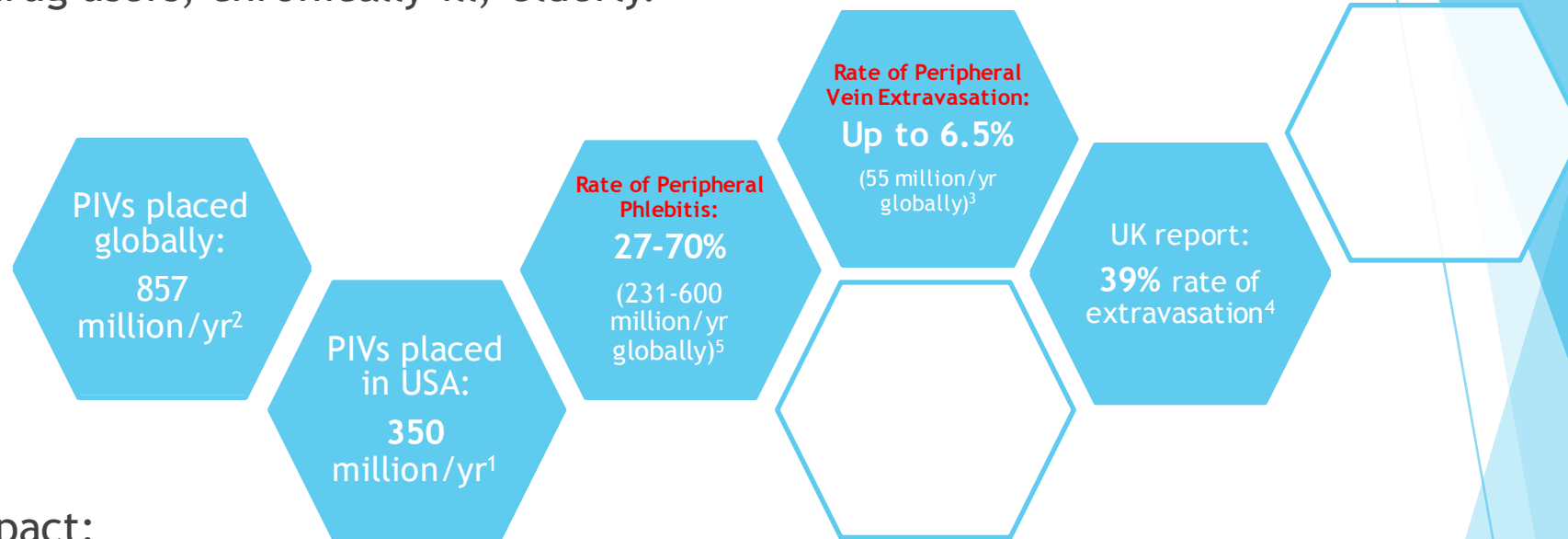


- ▶ Blood return during initial PIV placement may serve as an accurate indicator of PIV placement at the time of placement.
- ▶ When a PIV is placed and then not used for a day and re-accessed, determining that the PIV is still in the vein, has not migrated out, and is patent is essential to avoid vein phlebitis, drug extravasation and localized tissue damage.
- ▶ Due to low-pressure nature of peripheral veins, blood return is not an accurate indicator of PIV placement in a later phase of care.
- ▶ Subjective indicators such as patient reported pain or discomfort, and localized swelling or edema may not be reliable metrics of the placement and patency of PIVs in a later phase of care. Assessing for blood return is, “the most misleading of all signs [of a functional PIV] and has been implicated in a number of serious incidents” (Al-Benna, 2013).
- ▶ Based on clinical experience, bedside nurses are not always able to agree on whether or not a PIV is accurately placed or patent in that later phase of care.
- ▶ Inaccurate assessments can lead to unnecessary replacement of PIVs and potential extravasation and local tissue damage.

The Market and the Impact

- ▶ Patient's at risk: Chemotherapy, IV contrast recipients, peripheral vascular disease, IV drug users, chronically ill, elderly.

- ▶ Statistics:



- ▶ Potential Impact:

- ▶ USA: 115-266 million applications per year
- ▶ Global: 282-651 million applications per year

1. Smith's Medical: www.smiths.com/ar12/siteFiles/resources/pdf/report/26-31.pdf

2. Mike Toohey, Senior Project Leader, MarketLine (2015). Personal Communication.

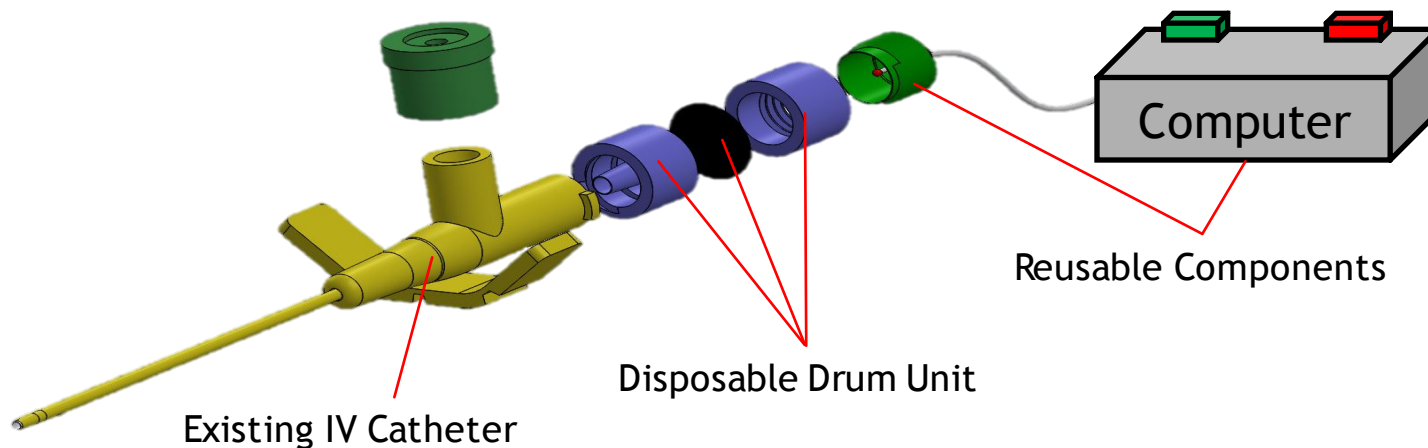
3. Sorrell DC. Developing extravasation protocols and monitoring outcomes. Journal of Intravenous Nursing 1998 July Aug;21(4):232-239.

4. Al-Benna. Extravasation injury in adults. ISRN dermatology. 2013, May.

5. Macklin D. Phlebitis: a painful complication of peripheral IV catheterization that may be prevented. AJN 2003 Feb 103(2):55-60.

Proposed Solution - “IVPlacedIt”

- ▶ Objectively determine if PIV is still within the vein and that the catheter is patent Attach directly onto any existing IV catheter by connecting to any existing PIV hub.
- ▶ Analyze venous pressure using high fidelity, micromanometer conductance catheter within a closed system.
- ▶ Display green light if PIV is still viable, red if not - Limiting user input and analysis
- ▶ Reusable Components: Pressure catheter and computer - isolating them from the sterile field and blood exposure.
- ▶ Disposable attachment to existing PIV, cost effective, connecting probe to catheter hub.
- ▶ Method: Separate continuous pressure waveform into single pressure beats → Average individual beats into single waveform → Compare length of time for beat and magnitude of waveform to physiological values



Development Plan

Within the next six months:

- ▶ Milestone 1: Complete bench testing to evaluate feasibility of pressure transduction in peripheral vein. If unsuccessful, will consider flow measurement (i.e. ultrasound).
- ▶ Continue to evaluate prior art. Current prior art review is promising.
- ▶ Milestone 2: Evaluate and finalize disposable “drum” materials which will transmit pressure from catheter hub to pressure transduction catheter.
- ▶ Milestone 3: Accurately interpret pressure readings into proprietary algorithm on external computer to display an easy-to-understand “Green” or “Red” indication of PIV usability.

Within the next 12 months:

- ▶ Milestone 4: Bench testing to evaluate accuracy of measurement in different structures (i.e. Adipose tissue, patent vessel, occluded vessel, muscle, etc.)
- ▶ Milestone 5: Acquire provisional patent protection.
- ▶ Milestone 6: Introduce the functional concept to potential licensees.

Projected Expenses

Description	Cost
High fidelity catheter	\$315
Pressure amplifier	\$1800
Data acquisition system	\$350
DAQ accessories	\$250 per prototype
Disposable pieces (3D printing)	\$200 per prototype
Legal filing fee	\$350 (Provisional) \$5,000 (International PCT)

Development Challenges

- ▶ Patient to patient variation in pressure readings.
- ▶ FDA Device Classification.
- ▶ Finding the right drum material.

The Team

- ▶ How we met? Engineering senior design team and healthcare application advisor.
- ▶ Accomplishments? Successfully license senior design project to medical device OEM.
- ▶ Team Members:
 - Han Jun Kim
 - University of Pennsylvania Dual Degree Graduate Student in Bioengineering & Embedded Systems.
 - Areas of expertise include implantable medical devices and medical device verification and validation.
 - Eric Dinges
 - University of Wisconsin Biomedical Engineering Graduate Student.
 - Areas of expertise include cardiovascular biomechanics, heart failure and diagnostic imaging.
 - Robert Anderson
 - Registered Nurse, Medical ICU at University of Iowa Hospitals and Clinics; Doctoral Nursing Graduate Student at University of IL Chicago.
 - Areas of expertise include critical care nursing and peripheral vascular access devices and technique.