Real-time Monitoring for Risk of Acute Kidney Injury
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History of Innovation

- Raman Gas Monitor (1986)
- NMB Monitor (1988)
- NICO Monitor (1990)
- Flow Sensor (1992)
- Drug Display (1994)
- QED (1996)
- Vapor-Clean (1998)
- Aneclear (2000)
- Safe Sedation Training (SST) (2002)
- Respiratory Depression Detection (2010)
- Virtual Reality Pediatric Distraction (2012)
- 2014
Deeply Embedded in Clinical Department

- ORs
- PACU
- ICU
- Floor
- Outpatient
- Sim Center
- Clinical Database
- Animal Facilities
- Volunteer Lab
- Bioeng. Lab
- College of Medical Informatics
- Dept. of Bioengineering
- Dept. of Medical Informatics
- Scientific Computing and Imaging Institute (SCI)
- College of Pharmacy
- Sim Center
- Volunteer Lab
- Bioeng. Lab
- Axon Medical
- Dynasthetics
- KORR
- Medvis
- anecare
- HAMILTON MEDICAL
- PHILIPS
- Dräger
- NIH
- NIH National Institute of General Medical Sciences
- National Heart, Lung, and Blood Institute
- American Heart Association
- National Center for Research Resources
Important Unanswered Question in Anesthesia & Critical Care

Ideal BP for Adequate Kidney Perfusion?
Cerebral Oxymetry

EKG Changes
Assumption

The Brain & Heart: Sensitive Monitors For Hypoperfusion
But....

Adequate Brain & Heart...

...Poor Renal Perfusion

Bellomo, Gianotomasso, 2001
Acute Kidney Injury (AKI) is Multifactorial

- Nephrotoxins
- Emboli
- Anemia
- Hypoxemia
- Blood Transfusion
- Hypoperfusion
Renal Injury ~ Up to 50%
AKI Incidence ~ 20-30%
Need for RRT ~ 2-6%
Acute Kidney Injury

- Mortality
- ICU Length of Stay
- Hospital Length of Stay
The Problem

Traditional Diagnosis
• Prolonged Oliguria (6-12 hrs)
• Rise in Creatinine

Biomarkers
• NAG, NGAL, TIMP-2, IGFBP-7, KIM-1
• Still only predictive 3-4 hrs after injury.

It takes hours to diagnose AKI
Late diagnosis precludes prevention.
Animal Studies: PuO2

Evans et al 2013
In Humans

PuO2 that remained below baseline after CPB

Predicted AKI after Cardiac Surgery

Kainuma et al 1996
Device Development → Bench Validation
**Natalie Silverton**, MD, Assistant Professor of Anesthesiology
- Fellowships in Cardiac Anesthesia, Thoracic Anesthesia, and Echocardiography. Double boarded in Emergency Medicine.
- Day to day clinical experience in hemodynamic management and the care of patients with multi-organ disease.
- Research in comparative physiology, cardiac anesthesia, echocardiography, and the detection of acute kidney injury

**Kai Kuck**, PhD, Professor of Anesthesiology
- Bioengineering, Innovation Management, Research Director
- Former Head of Research at major global med device co.
- Research: Pharmacokinetic/dynamic visualization, signal processing, hemodynamic monitoring, intelligent systems

**SWS Medical Ventures**
- Experienced Utah research company with know-how in developing clinical fiber optic based sensors
- ISO 13485 quality systems, regulatory expertise will help in subsequent transitioning towards an FDA 510(k) and CE (Europe) cleared medical product.
Device Development

Bench Validation

Subj #58 out of 100

Clinical Studies
(Cardiac Surgery, Sepsis, Renal Transplant)

Development and Validation of a Protocol for Renal Hypoxia

Basic Science
(Autoregulation, Vasopressors, Fluid Management)
QUESTIONS FOR THE PANEL

• how far should we drive the maturity of this technology?
  • proof of principle / feasibility
  • 510(k)
  • manufacturing
  • regional/national/global sales

• what is the best option for exiting / developing our business
  • sublicensing to vs partnering with established players in the market?
  • begin our own (or contract) manufacturing?
  • beginning our own distribution/sales?

• what do we need to pay attention to with respect to reimbursement aspects?
• is it sufficient to get IP protection in the US? (which other countries?)
• $$$
  • how much can we expect to need?
  • options for raising those funds