The Wireless Health Solution Path

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Complete Process (Epic Adventure) Highlight Examples of 2015-2016

• 2015 - 2016
• **Completed**
• SEM Scanner
  – First evidence-based method for pressure ulcer detection.
  – On market in UK, EU, Canada
  – *Received 2015 Frost & Sullivan Innovative Medical Device Award*
• **AbStats:**
  – First Human Digestion Monitor
  – *FDA 510(k) clearance in less than 9 months*
  – Successful trials, *three awards at Digestive Disease Week conference, entering marketplace*
• **In Development**
• Product Firsts:
  – Healthcare and consumer Wireless Health systems in advanced development
• Mental Health and Wellness:
  – Wireless Health Products for UCLA Depression Grand Challenge (DGC)
  – Wireless Health monitoring of cohort of *all of 100,000 subjects for 10 years*
  – Wide range of new products directed to advancing mental health and wellness
Wireless Health Institute (WHI)

- WHI Mission
- End-to-End *Current Product Development*
  - Wound Diagnostics and Care
  - Orthopaedic Health
  - Digestive Process Monitoring
  - Motion, Posture, and State Classification
  - Human Performance Advancement
  - Patient Guidance
  - Mental Health and Wellness
Wireless Health Product Development is a New Process

- Contrast with conventional Information Technology
  - Development occurs in centers of innovation that may be independent of a formal development environment
  - “The next social media breakthrough industry is being developed in a garage – somewhere”

- Wireless Health product development fundamentally requires the innovation center to be in or associated with a healthcare provider environment
Wireless Health Product Process

Concept

Led by Clinician Expert

Science

Foundation Methods

Transducer

Efficacy

Safety

Analytics

Accuracy

Specificity

Regulatory

First Trials

Critical Refining Stage*

Regulatory
Wireless Health Product Process

1. Design
2. Product
3. Production
4. Trials
5. CE Mark

- IP
- Define
- Plan
- Validation
- IEC Certification

- License
- Regulatory
- Regulatory
- Partnership
Wireless Health Product Process

- FDA
- Presubmission
- Submission
- Production
- Delivery

1. Application Preparation (over 100 documents)
2. Refinement
3. Partner Support for Approval
4. Contract Manufacturing Support
5. Partner Support Trials
6. Partner Support
Wireless Health Product Example:

First Evidence-Based Detection of Pressure Ulcers
Acute Need for Detection and Classification of Pressure Ulcers

• Pressure ulcers induced by continuously applied excessive pressure to tissue

• Pressure ulcers lead to:
  – Pain, disfigurement, slow recovery
  – 60,000 deaths annually
  – Treatment cost of 140,000 USD
  – Longer hospital stays (currently accounts for over 2.5 million Medicare hospital days in US)

• Prevalence of pressure ulcers
  – 10% to 14% among hospitalized patients of all ages
  – 24% among patients in nursing homes.

Quality Indicators for Prevention and Management of Pressure Ulcers in Vulnerable Elders, Barbara M. Bates-Jensen
Pressure Ulcers

• Treatment challenge
  – Patient care support inadequate
  – Patients repositioned (turned) far less often that required
  – Wound exists below tissue surface
  – Visual inspection is current standard
  – Wound classification challenging
  – Visual inspection not effective for subjects with darkly pigmented skin
The Wireless Health SEM Scanner

- Commitment to Mission
  - Discovery of unmet need for a *global product*
  - Led by Dr. Barbara Bates-Jensen
- Science Foundation
  - Characterize subepidermal moisture
- Development of Solution
  - Dielectric characterization of tissue
- Development Trials Phase
- Validation Trials Phase
- Licensing of technology to Bruin Biometrics (BBI)
- Regulatory Phase
- Production
- Trials Validation
- CE Mark Certification
- FDA Approval Process
SEM Scanner Today

• On market in EU, UK, and Canada
  – Many leaders completed trials of SEM Scanner products in 2015
    • Royal Albert Edward Infirmary demonstrated dramatic reduction in pressure ulcer occurrence
  – Adoption by multiple providers, Virgin Care, Health Canada

• Received Frost and Sullivan Innovative Medical Device Award – 2015

• See recent Wall Street Journal interview video
  – Health 360 Interview with CEO BBI (August 11)
Wireless Health Product Example:

First Wearable Monitoring of Human Digestion
International Burden of Digestive Disease: An Unmet Need

• Population Impact
  – 70 million Americans suffer from digestive diseases
  – Inflammatory Bowel Diseases (Ulcerative Colitis and Crohn’s Disease)
    • 10 – 15 percent of US population

• Mortality
  – Nearly 10 percent of all deaths

• Hospitalization
  – 10 percent of all hospital admissions
  – Outpatient treatment – GI endoscopy examinations alone over $30 billion.

• Abdominal Pain
  – 16M Clinic Visits
  – 5M Emergency Room Visits with 21 percent leading to hospitalization

• Readmission for colorectal surgery
  – Highest rate of readdmission of surgical procedures
Gastrointestinal Engine

Esophagus
• Ingestion

Stomach
• Food blend
• Protein extraction
• Food bolus sequencing

Duodenum
• Food bolus arrival sensing
• Gastric acid processing
• Iron absorption

Small Intestine
• Fat digestion
• Carbohydrate digestion

Large Intestine
• Water absorption
Gastrointestinal Disorders

Esophagus
- Dysphagia
- Stroke Conditions
- Cancer

Stomach
- Delayed emptying
- Gastroparesis
- Bariatric surgery complications
- Cancer

Duodenum
- Ulcer
- Inflammation
- Diverticulum
- Cancer

Small Intestine
- Inflammatory Bowel Disease
- Cancer

Large Intestine
- Irritable Bowel Syndrome
- Cancer
Current Monitoring Methods
Non-Invasive, Constantly Vigilant Digestive Monitoring

- **Esophagus**
  - Peristalsis
  - Chewing

- **Stomach**
  - Contractions
  - Pyloric valve contractions
  - Food transport

- **Duodenum**
  - Peristalsis events
  - Food transport

- **Small Intestine**
  - Peristalsis events
  - Food transport

- **Large Intestine**
  - Peristalsis events
  - Food transport
AbStats Wearable and Disposable Digestive Monitor Multisensor System Broadband Vibrational Wave Detector

Wearable
Over 70 Subjects

Disposable
UCLA Reagan GI Surgery
AbStats Signals: Healthy Subject Peristalsis Event
AbStats Signals: Healthy Subject
Peristalsis Event
Post Operative Ileus (POI) Monitoring:

- Estimated 2.7 million abdominal operations performed in U.S. annually
  - Number growing as population ages

- POI
  - Nearly 1 million cases annually of severely delayed digestive function

- Direct costs of care
  - POI total direct costs: $1.46 billion annually
  - POI vs. non-POI LOS: 11.5 vs. 5.5 days
  - POI 30 day readmissions rate: 10%

Asgeirsson et al. *J Am Coll Surg* 2010;210:228–231
Goldstein et al. *P&T* 2007;32:82-90
Standard of Care for Post-Operative Ileus

• Patient Self-Reporting
  – Inaccurate

• Manual stethoscope monitoring
  – Requires physician in attendance
  – Fundamental limitations
    • Events rarely occur
    • Events may be inaudible

• Patient Examination
  – Interview
  – Physical appearance
Post-Operative Feeding: A Delicate Balance

The Problem: Most surgeries paralyze the bowels temporarily. It’s hard to know when to confidently feed after surgery.

Feed Too Soon
- Discomfort
- Vomiting
- Aspiration
- Pneumonia
- Early readmission
- Death

Feed Too Late
- Delayed nutrition
- Poor wound healing
- Increased infection
- Need for expensive parenteral nutrition
- Early readmission

Prolonged length of stay = $1.46 billion
Managing Postoperative Feeding: AbStats First Product Target

- 55 million operations in U.S. annually
- 10 million operations with high risk of slowing bowel function
  - 4.5 million at greatest risk of slow bowel function
  - ~1 million cases of severely delayed bowel function
  - All require anesthesia that can slow bowel function
  - Operations that increase risk beyond anesthesia alone
    - Abdominal, pelvic, and urological operations with highest risk for slowing bowels
    - *Post-operative ileus*: the most severe and costly result of slowed bowel function
  - Initial AbStats target

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AbStats Ileus Classification Trial

• AbStats Ileus Detection
  – Abdominal broadband vibration signal monitoring
  – Self-calibrating system
  – Wearable belt

• Over 70 subjects at Veteran’s Administration Hospital
  – Wide range of conditions corresponding to disorders and treatment.
AbStats Ileus Trials Results

[Diagram showing motility event rate (events/sec) for Post Surgery No Nutrition, Post-Surgery Returning to Nutrition, and Healthy Subject categories.]
Potential to become part of standard post-op orders for 4.5+ million patients

Post-op orders

- Transfer to PACU
- Diet NPO
- Check vitals q2h
- D5 ½ NS 100cc per hour IV
- **AbStats q 8 hours**
- Pulse-ox
- PCA pump per protocol

MD

Dr. Chang

Signature
AbStats Motility:
Example of Full Recovery
AbStats Motility Tracker
Example of Full Recovery

![Graph showing motility metric over postoperative days.](image)
AbStats Motility Tracker
Example of Severe Post-Op Ileus
New Trial – Prediction of Post-Operative Ileus

- **Trial Population**
  - 28 subjects
  - 9 developed POI

- **Conclusion from clinician team**
  - Non-invasive, abdominal, acoustic monitoring prospectively predicts POI.
  - Surgeons may use AbStats to rule-out POI with over 80% certainty
Comparison of Post-Operative Day 1 and 2 Intestinal Rate Predicts POI

Post-Operative Gastrointestinal Telemetry with an Acoustic Biosensor Predicts Ileus vs. Uneventful GI Recovery

Marc Kaneshiro, MD; William Kaiser, PhD; Phillip Flesher, MD; Marcia Russell, MD; Anne Lin, MD; Karen Zaghian, MD; Jonathan Pourmorady, MD; Bibiana Martinez, MPH; Anish Patel, MD; Amy Nguyen, MS; Digvijay Singh, MSE; Vincent Zegarski, BSEE; and Brennan Spiegel, MD, MSHS.
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DDW Plenary Presentation and Award
Physician-Delivered Malnutrition: Why Do Patients Receive Nothing by Mouth or a Clear Liquid Diet in a University Hospital Setting?

Glen A. Franklin, MD; Stephen A. McClave, MD; Ryan T. Hurt, MD; Cynthia C. Lowen, RD; Allyson E. Stout, RD; Lisa L. Stogner, RD; Nicole L. Priest, RD; Mary E. Haffner, RD; Karl R. Deibel, PharmD; Dana L. Bose, RD; Barbara S. Blandford, RD; Tyler Hermann; and Mary E. Anderson, RD

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Background: Traditional practices of placing patients nil per os (NPO) or on clear liquid diet (CLD) deter delivery of optimal nutrition care and are not always supported by sound physiologic principles. Objective: This perspective survey evaluated the incidence of this practice, the reasons for such orders, and the response to intervention by the Multidisciplinary Nutrition Team (MNT). Methods: All patients admitted to University of Louisville Hospital were monitored by MNT dietitians and were candidates for the study if they were placed NPO upon CLD for 23 days. The MNT determined appropriateness of diet orders. Results: Out of 1192 admissions, 22.6% of the patients (n = 262, 61% male, mean age 46.1 years) were found to be NPO or on CLD for 23 days (mean 5.2 days NPO, 1.04 days CLD), and were entered in the study. Uncertainty regarding the reason for the specific diet order occurred more often when patients were placed on CLD than when made NPO (32.1% vs. 15.0% of cases, respectively, P < 0.05). NPO diet orders were more often deemed appropriate by the MNT than were orders for CLD (58.6% vs. 25.6%, respectively, P < 0.05). Compliance with MNT recommendations was low at 40.0%. Conclusions: Despite an active MNT, 22% of patients were made NPO or placed on CLD for a prolonged period of time. More than a third of diet orders for NPO and two thirds of orders for CLD were inappropriate and poorly justified. Improving the adequacy of nutrition therapy is hindered by noncompliance with MNT recommendations. (JPEN J Parenter Enteral Nutr. 2011;35:337-342)

Keywords: nothing by mouth; clear liquid diet; enteral nutrition
Gastrointestinal Engine

Esophagus
- Ingestion

Stomach
- Food blend
- Protein extraction
- Food bolus sequencing

Duodenum
- Food bolus arrival sensing
- Gastric acid processing
- Iron absorption

Small Intestine
- Fat digestion
- Carbohydrate digestion

Large Intestine
- Water absorption
AbStats Transport Metric

• Nutrition Transport System
  – Characterize time and energy cost of food processing
  – Enable optimization of delivery of nutrition

• Nutrition Transport Processes
  – Hydrodynamic flow in complex elastic contractile tissue
  – Characteristic waveforms indicate location, quantity, type of food contained in food bolus
Next Step: Optimizing Nutrition Across All Subjects

• Nutrition Process Optimization
  – Delivery of proper nutrition
  – Optimization of nutrition schedule relative to:
    • Individual goals
    • Weight management
    • Wellness,
    • Well-being
    • Sleep quality
    • Athletic performance
  – Individualized per subject
Wireless Health Products for Orthopaedic Joint Monitoring
Orthopaedics: Joint Health

• Urgent Need: Detection of Joint Disorders
  – Detect onset and progression of osteoarthritis and rheumatoid arthritis
  – Detect debilitating wear and risk of failure and injury in prosthetic joints

• Orthosonos System:
  – Exploit novel high frequency acoustic emission signal processing to characterize joint state.
  – New wearable sensor system
  – Signal processing and classification system
Orthopaedic Acoustic Joint Monitoring: Prosthetic Trials

ROC Area = 0.90
Classification of Orthopaedic Joint State: Arthritic Natural Joints

• Fundamental friction phenomena induces stick-slip events at joint surfaces
  – Associated acoustic emission signatures observed to depend on joint state
  – Classifier system implemented for joint state diagnostic

• Application to natural joints
Wireless Health Products in Mental Health and Wellness
The UCLA Grand Challenge Project: Eliminating the Burden of Depression
Depression is the leading cause of disability in North America

US healthcare costs for mood disorders were $231B in 2010

PricewaterhouseCoopers LLC, 2012
Depression

• Results from a complex interaction of social, psychological and biological factors.
• By 2030, depression will be the leading contributor to the global burden of disease.
• Annually, 800,000 people worldwide, most of them depressed, take their own life. This loss of life is greater than for all current wars combined.
• Depression also exerts a huge economic toll. It stops people from working and impairs education.
Products for Mental Health and Wellness

• UCLA Depression Grand Challenge (DGC)
  – A new research model with over 100 faculty from more than 20 departments engaged
  – Led by Dr. Nelson Freimer

• DGC Multi-Decade Goals: 100K Subjects
  – Determining the causations of depression including neurogenetics through diverse cultures and populations
  – Developing interventions that exploit continuously available remote monitoring and remote guidance based on proven methods now available and to be developed.
Conclusion

• Continuous Wireless Health monitoring has proven fundamental benefits

• Next phase of Wireless Health will enable *guidance*
  – Health and Wellness (physical and mental)
  – Treatment and Recovery
  – Human Performance

• Wireless Health will deliver the most valuable and largest global information resource in history