Mobile and Wireless Technologies to Improve Health

William Riley
National Heart, Lung, and Blood Institute
Chair, NIH mHealth Interest Group
May 3, 2012
What is mHealth?

• The use of mobile and wireless devices to improve health outcomes, healthcare services, and health research
  – NOT JUST PHONES
  – Not all Wireless is Mobile (e.g. laptops)
  – Not all Mobile is Wireless (e.g. basic Pedometer)
Leveraging the Ubiquity of the Mobile Wireless Infrastructure
Ecological Momentary Assessment
Implantable Biosensors

- **Problem:** Measurement of analytes (glucose, lactate O2 and CO2) that indicate metabolic abnormalities
- **Solution:** Miniaturized wireless implantable biosensor that continuously monitors metabolism
  - Inserted by needle subcutaneously
  - Operated remotely using a PDA
  - Multi-analyte sensor
  - One month continuous monitoring

Diane J. Burgess, University of Connecticut
NHLBI, R21HL090458
Stress Hormone Detection

- **Problem:** Detection of salivary stress hormones in real-time is expensive and not practical in clinical settings
- **Solution:** Develop wireless salivary biosensors
  - Salivary α-amylase biosensor
  - Salivary cortisol biosensor

Vivek Shetty, DDS, UCLA, NIDA
U01DA023815
Wearable Chemical Sensor System

- **Problem:** Chemical exposure varies by context, need personal exposure
- **Solution:** Selective detection of VOCs (hydrocarbon and acid vapors)
  - Sensitive: ppb – ppm
  - Real-time: sec. – min.
  - Spatially resolved
  - Wearable: cell phone size
  - Cell phone based interface

Nongjian Tao, Arizona State University, NIEHS, U01 ES016064

[http://www.airnow.gov](http://www.airnow.gov)
Population Scale Activity Measures

• **Problem:** Population-scale measurement of physical activity

• **Solution:** Miniature, low-cost devices that measure human motion using redesigned accelerometers

Stephen Intille, PhD, Northeastern University
NHLBI, U01HL091737
LUCAS- Mobile Microscope

**Problem:** Create a low-cost quality microscope to use in low resources settings.

**Solution:** A specially-developed lens fits to a cell phone to create a microscope

**Field testing:** Malawi, Mozambique and Brazil

LUCAS images of CD4+ and CD8+ T cells compared to a regular microscope image

Karin Nielsen, UCLA, FIC, R24TW008811
Molecular Analysis of Cells

**Problem:** Detection a variety of biologics rapidly and without a laboratory.

**Solution:** A chip based micro NMR unit Smartphone powered analysis: Ca Protein bio-markers, DNA, bacteria and virus drugs

Ralph Weissleder, MIT, NIBIB RO1 EB004626
Intervention
Rely on Health Professionals for Output

User

Inputs

Integration & Analytics

Health Professional
Weaknesses of the Health Professional

Closing the Loop

• Drinking through a firehose
  – Set alert parameters
  – Optimize healthcare interface

• Data = Liability

• Assumes Appropriate Treatment

Univ. of Maryland
Human Computer Interface Lab
Feedback to the Patient

Inputs

User

Integration & Analytics

Typical fluctuation within a day

Blood Pressure

- Systolic Blood Pressure
- Diastolic Blood Pressure

- Arriving at Work
- Telephone Conversation
- Argument
- Leaving Work
- Sleep

6AM 12PM 6PM 12AM

Morning Afternoon Evening
Behavior Change in ≤ 160 Characters

Inputs

User

Integration & Analytics

Free msg: Only use medicines that your Dr. says are OK. Always use the dropper that comes with the medicine. Make sure it is the right dose for an infant.
**Cardiac Disease Management**

**Problem:** Patients with CVD have symptoms that frequently bring them to emergency care where there is limited baseline data

**Solution:** Remote monitoring to create physiological cardiac activity “fingerprints” that alert professionals and patient when there are irregularities based on their own cardiac patterns

Vladimir Shusterman, PinMed, NHLBI, R43-44 HL0771160, R41HL093953
Chronic Disease Management

• **Problem:** Chronic diseases are difficult and expensive to manage within traditional healthcare settings
• **Solution:** CHESS: Disease self-management programs for asthma, alcohol dependence and lung cancer
  • Information provided the user needs it
  • Intervene remotely with greater frequency than traditional care
    – Real-time management
    – More efficient triage
    – Reduces acute care

David Gustafson, University of Wisconsin, NIAAA R01 AA 017192-04
Body Sensor Networks

• **Problem:** Overweight and Obesity among urban, minority youth
• **Solution:** KNOWME networks personalized monitoring & feedback in real-time
  □ Immediate access to data allows nimble reactions to events, environments, & behavior
  □ User interface for health professionals, children & families

Donna Spruijt-Metz, PHD, USC, U54-CA-116848
Expanding Our Output Modalities

- On demand video trainings
- Rich media presentations
- Proactive social support
- Monetary incentives via mBanking, etc.
- Adaptive
  - To behavioral context
  - To prior intervention responses
- Theoretically and Empirically Grounded – especially in behavior change
Technology Outpaces RCTs

2005
Grant Submit and Award

2006
Development and Pilot Testing

2007
Recruit and Randomize

2008

2009
Follow-ups

2010

2011
Analyze and Publish

YouTube

iPhone

Android

iPad
Interpreting RCTs of Dated Technologies – An Example

  – 1653 patients hospitalized for heart failure
  – Randomly assigned to telemonitoring or usual care
  – Readmit or death within 6 months
  – Difference: 52.3% vs. 51.5%
  – Conclusion: “Telemonitoring did not improve outcomes”

• The telemonitoring condition:
  – IVR daily report of symptoms and weight
  – Flagged variances reviewed by patient’s clinicians;
  – Protocol required responses and documentation (but adherence to responding not reported)
Streamlining mHealth RCTs

- Speed or bypass development
  - Evaluate existing applications
  - Open source or access (eliminate 1 off dev)
  - Modular, component oriented development

- Leverage mobile technologies
  - Recruitment
  - Assessment
  - See Pfizer REMOTE trial

- Simple, Pragmatic Trials
  - Focus on core components

- Shorten follow-ups
  - Evaluate proximate outcomes
  - Model or simulate more distal outcomes
Remote Clinical Trials

Do you have Overactive Bladder (OAB)?

Find yourself rushing to the bathroom?

Wishing you could get there on time?

You may be eligible to participate in a 16-week clinical research study sponsored by Pfizer, conducted under FDA regulations and overseen by the University of California, San Francisco.

Why participate?

- Help advance research and potentially help others with OAB symptoms.
- You can participate in the privacy and comfort of your home!
- Get paid $25 for each online assessment and/or lab visit completed. Get paid up to $175.

You will be paid for your time and effort and you can participate from home.
Alternative RCTs for Alternative Questions

• Which combination of components optimize outcome?
  – Factorial or Fractional Factorial Designs
    • See Collins et al., Psychol Methods, 2009; 14: 202-24

• What sequence of components optimize outcome?
  – Adaptive Trials
  – Sequential Multiple Assignment Randomized Trial

N of 1 – ABA Design

• Baseline
  • Multiple assessments
  • Need stability
  • Prefer non-trending (see Salanas et al., Beh Mod, 2010;34-195-218 for baseline trend correction)

• Intervention
  • Rapid effects
  • Sustained during intervention
  • Trending a plus

• Return to Baseline
  • Withdraw treatment
  • No lasting intervention effects

• Analysis
  • Visual inspection
  • Paired t-tests
  • SD Bands (2 or 3 SDs)

• Variants
  • Replication
  • Staggered Replication

• Graph – Social Skills Intervention for Autism
  • Gutman et al. Occup Ther Int 2010; 17:188-197
Control System Engineering Modeling

- Generate hypothesized systems of mediators and moderators affecting outcome
- Iterate and refine from rich longitudinal data sets of individuals
- Close the loop via proposed intervention
- Iterate and test in multiple individuals

Riley et al, Transl Behav Med. 2011;1: 53–71
Interrupted Time Series

- Use baseline data points to estimate CI of future data points
- Intervention with hypothesis that future data points will exceed CI
- Strengthened by control (as here) or staggered intervention
- RFID system to reduce healthcare wait times
Stepped Wedge Design

- Sequential roll-out by individuals or cohorts over multiple time periods
- Random assignment of intervention timing
- All eventually receive treatment
- Excellent example from Gambia Hepatitis Study

Shaded cells represent intervention periods
Blank cells represent control periods
Each cell represents a data collection point
NIH mHealth Efforts

• NIH two mobile and wireless health groups
  – mHealth IIIG with 100 NIH members
  – Medical Wireless Workgroup (NIBIB). Members from multiple federal agencies
• Organizing sponsor of the mHealth Summit (2009-2011)
• mHealth Training Institutes (OBSSR)
• mHealth Evidence Workshop: RWJ, McKesson & NSF to better match research design to the pace of mHealth technology development (August, 2011)
• NIA/NIBIB Personal Motion Sensing meeting (June, 2010)
• NCI RADAR activity sensor test-bed program
• Coming Soon: mHealth Common Fund Initiative