mHealth at the National Institutes of Health (NIH)

Wendy Nilsen, PhD
Office of Behavioral and Social Sciences Research (OBSSR)
NIH/DHHS

http://obssr.od.nih.gov
Office of Behavioral and Social Sciences Research (OBSSR) Mission

... to stimulate behavioral and social science research throughout NIH and to integrate these areas of research more fully into others of the NIH health research enterprise, thereby improving our understanding, treatment, and prevention of disease.
Living in the Digital Age
What is mHealth?

• Diverse application of wireless and mobile technologies designed to improve health research, health care services and health outcomes

• NOT JUST CELL PHONES
Includes any wireless device carried by or on the person that is accepting or transmitting health data/information

- Sensors (e.g., implantable miniature sensors and “nanosensors”)

- Monitors (e.g., wireless accelerometers, blood pressure & glucose monitors)

- Mobile phones
Beyond Telemedicine

- **Portable**: Beyond POC Diagnostics
- **Scalable**: Economical to scale
- **Richer data input**: Continuous data sampling
- **Personal**: Patient can receive & input information
- **Real-time**: Data collection and feedback is in real-time using automated analyses and responses
The Potential

- mHealth technologies can expand health into the real world.
- Generate user-friendly tools for enhancing health.
- Change the questions we ask.
- Remote clinical trials offer new possibilities.
Who uses Mobile?

Everyone

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### Demographics of cell phone users

% of all adults in each group who have a cell phone

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>82%</td>
</tr>
<tr>
<td>Men</td>
<td>83%</td>
</tr>
<tr>
<td>Women</td>
<td>81%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>90%</td>
</tr>
<tr>
<td>30-49</td>
<td>88%</td>
</tr>
<tr>
<td>50-64</td>
<td>82%</td>
</tr>
<tr>
<td>65+</td>
<td>57%*</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>80%</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>87%*</td>
</tr>
<tr>
<td>Hispanic, English-speaking</td>
<td>87%*</td>
</tr>
<tr>
<td>Household Income</td>
<td></td>
</tr>
<tr>
<td>Less than $30,000</td>
<td>71%*</td>
</tr>
<tr>
<td>$30,000-$49,999</td>
<td>82%</td>
</tr>
<tr>
<td>$50,000-$74,999</td>
<td>90%</td>
</tr>
<tr>
<td>$75,000+</td>
<td>93%</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>Less than High School</td>
<td>72%</td>
</tr>
<tr>
<td>High School Diploma</td>
<td>76%</td>
</tr>
<tr>
<td>Some College</td>
<td>86%</td>
</tr>
<tr>
<td>College+</td>
<td>90%*</td>
</tr>
</tbody>
</table>

* indicates a statistically significant difference.

Source: Pew Research Center's Internet & American Life Project, April 29 - May 30, 2010 Tracking Survey. N=2,252 adults 18 and older; n=1,917 based on cell phone users.
What are the components of Mobile?

- **Interactive Voice Response (IVR)** is a technology that allows a computer to interact with humans through the use of voice and keypad inputs.
- IVR allows people to access a database via keypad or by speech recognition to get information or receive services by following the instructions.
- IVR systems can respond with prerecorded or dynamically generated audio to provide information, support or intervention.
What are the components of Mobile?

- Text Messaging - Officially called Short Message Service (SMS) is the text communication service component of phone,
- SMS is the most widely used data application in the world, with 2.4 billion active users, or 74% of all mobile phone subscribers
- SMS messages are very brief - Not usually over 160 characters
- Consumers do not like when professionals use SMS slang (LOL) or emoticons ;)
SMS Text Messaging

Not Limited to the young

Median number of calls on a typical day, by age

Based on American adults with cell phones

- 18-29: 10 calls
- 30-49: 8 calls
- 50-64: 5 calls
- 65+: 3 calls

Source: Pew Research Center's Internet & American Life Project, April 29 - May 30, 2010 Tracking Survey. N=2,252 adults 18 and older; n=1,917 based on cell phone users.
What are the components of Mobile?

- Wireless Internet through smart phones
- Smartphone operating systems can access the web to provide interact web streaming.
- Can be used as a data collection device (contains a camera, pedometer, heart rate monitor, self-report, etc) or as an intervention tool to provide feedback to clients with a web interface
Wireless internet use, 2009-2010

The % of all adults who do the following

- **April 2009**
  - Go online wirelessly with laptop: 39
  - Go online wirelessly with cell phone: 32
  - Go online wirelessly from cell or laptop: 51

- **May 2010**
  - Go online wirelessly with laptop: 47
  - Go online wirelessly with cell phone: 40
  - Go online wirelessly from cell or laptop: 59

Source: Pew Research Center's Internet & American Life Project, April 29-May 30, 2010 Tracking Survey. N=2,252 adults 18 and older. Cell phone wireless users include those who use email on a cell phone; use the internet on a cell phone; or use instant messaging on a cell phone.

African-Americans and Latinos lead whites in their use of mobile data applications

<table>
<thead>
<tr>
<th></th>
<th>All adults</th>
<th>White, non-Hispanic</th>
<th>Black, non-Hispanic</th>
<th>Hispanic (English-speaking)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own a cell phone</td>
<td>82%</td>
<td>80%</td>
<td>87%*</td>
<td>87%*</td>
</tr>
<tr>
<td>% of cell owners within each group who do the following on their phones</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take a picture</td>
<td>76</td>
<td>75</td>
<td>76</td>
<td>83*</td>
</tr>
<tr>
<td>Send/receive text messages</td>
<td>72</td>
<td>68</td>
<td>79*</td>
<td>83*</td>
</tr>
<tr>
<td>Access the internet</td>
<td>38</td>
<td>33</td>
<td>46*</td>
<td>51*</td>
</tr>
<tr>
<td>Send/receive email</td>
<td>34</td>
<td>30</td>
<td>41*</td>
<td>47*</td>
</tr>
<tr>
<td>Play a game</td>
<td>34</td>
<td>29</td>
<td>51*</td>
<td>46*</td>
</tr>
<tr>
<td>Record a video</td>
<td>34</td>
<td>29</td>
<td>48*</td>
<td>45*</td>
</tr>
<tr>
<td>Play music</td>
<td>33</td>
<td>26</td>
<td>52*</td>
<td>49*</td>
</tr>
<tr>
<td>Send/receive instant messages</td>
<td>30</td>
<td>23</td>
<td>44*</td>
<td>49*</td>
</tr>
<tr>
<td>Use a social networking site</td>
<td>23</td>
<td>19</td>
<td>33*</td>
<td>36*</td>
</tr>
<tr>
<td>Watch a video</td>
<td>20</td>
<td>15</td>
<td>27*</td>
<td>33*</td>
</tr>
<tr>
<td>Post a photo or video online</td>
<td>15</td>
<td>13</td>
<td>20*</td>
<td>25*</td>
</tr>
<tr>
<td>Purchase a product</td>
<td>11</td>
<td>10</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>Use a status update service</td>
<td>10</td>
<td>8</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>Mean number of cell activities</td>
<td><strong>4.3</strong></td>
<td><strong>3.8</strong></td>
<td><strong>5.4</strong></td>
<td><strong>5.8</strong></td>
</tr>
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N=2,252 adults 18 and older, including 1,917 cell phone users. * = statistically significant difference compared with whites.
# Young adults lead the way in the use of mobile data applications

<table>
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<tr>
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</tr>
<tr>
<td>Watch a video</td>
</tr>
<tr>
<td>Post a photo or video online</td>
</tr>
<tr>
<td>Use a status update service</td>
</tr>
<tr>
<td>Make a purchase</td>
</tr>
</tbody>
</table>

**Mean number of cell activities**

6.9  4.7  2.5  1.2

Source: Pew Research Center's Internet & American Life Project, April 29-May 30, 2010 Tracking Survey. N=2,252 adults 18 and older, including 1,917 cell phone users. *** = significant difference compared with all other age groups; ** = significant difference compared with 50-64 and 65+; * = significant difference compared with 65+; n/a = sample size too small to analyze.
How many apps are there?

- In June 2010 there were
  - 225,000 apps in the iTunes App Store – Store opened July 2008
  - 100,000 apps in the Google Android app store – Store opened October 2008
- By 2015, 500,000 Consumers projected for mHealth apps on smartphones (research2guidance, 11/2010)
NIH mHealth Activities
Continuum of mHealth tools

Measurement
- Sensor sampling in real time
- Integration with health data

Diagnostic
- POC Diagnostics
- Portable imaging
- Biomarker sensing
- Clinical decision making

Treatment
- Chronic disease management
- Remote Clinical trials
- Disaster support/care

Global
- Service Access
- Remote treatment
- Dissemination of health information
- Disease surveillance
- Medication tracking and safety
- Prevention and wellness interventions
Measurement and 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 cell phone
  - Multi-analyte sensor
  - One month continuous monitoring

Diane J. Burgess, University of Connecticut
NHLBI, R21HL090458
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
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
Population Scale Activity Measures

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

• **Solution:** Miniature, low-cost devices that measure human motion using redesigned accelerometers in a user-friendly format

Stephen Intille, PhD, Northeastern University
NHLBI, U01HL091737
Diagnostics
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

Cell phone transmits image

Karin Nielsen, UCLA, FIC, R24TW008811
High-resolution fiber-optic microendoscope

- **Problem:** Methods to detect cancer from traditional biopsies are invasive for patients and require lab facilities.
- **Solution:** A scientific charge-coupled device camera and a laptop computer for under $4,000 (clinical trials in China, Botswana, Guatemala)

Rebecca Richards-Kortum, Rice Univ.  
NIBIB RO1 EB007594
Treatment
Body Sensor Networks

**Problem**: Overweight and Obesity among urban, minority youth

**Solution**: KNOWME networks personalized tracking & feedback in Real-Time

- Immediate access to data allows nimble reactions to events, environments, & behavior
- User interface for health professionals, children & families
- User initiated data (SMS, speech notes, images/videos)
- Real-time, personalized, adaptive interventions to correct energy balance

Donna Spruijt-Metz, PHD, USC, NSF
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
**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
Wireless Pain Prevention Program

- **Problem:** Treatment of pain and quality of life improvement for youths with Sickle Cell Disease
- **Solution:** Wireless Pain Prevention Program
  - Cell phone with e-Ouch software (support and information for pain in real-time)
  - Web link connecting to educational materials, a psychologist, and a nurse practitioner
  - Peer social support network through cell phone

_Eufemia Jacob, UCLA, NHLBI, RC1HL100301_
Aging in Place: Smart Environment/Mobile Technologies

- **Problem:** Assessment of and intervention for everyday functional limitations of persons with early-stage dementia without need of assisted living (aging in place)
- **Solution:** Automated wireless and fixed monitoring and assistance to help people cope with age-related limitations

Diane J. Cook, Washington State NIBIB, R01EB009675
Global
Necessity for Global Health

- Lack of providers in developing world
- No wired infrastructure
  - Well-developed and rapidly growing wireless
- Healthcare needs to be provided through low-cost and immediate, scalable services
- Potential for reverse technology transfer
  - Knowledge from developing world informs domestic research and practice
**Problem**: Adherence to chronic disease medications is poor. In resource-poor settings, getting people medication is only part of the solution

**Solution**: Wireless medication canisters that signal medication timing, transmit adherence data and allow resources to target the non-compliant
Adverse Event Monitoring (Peru)

**Problem:** Following at-risk patients for adverse events in low- to medium resource countries is expensive/impractical

**Solution:** Wireless adverse events reporting and database improves patient and community care

- Real time data via IVR on cell phones
- Queries on demand via Internet
- Real time alerts via E-mail
- Real time alerts via SMS
- Urban and rural areas of Peru
- Secure database
- Communication back to the field via cell phones

Walter Curiso, MD, University of Peruana
FIC R01TW007896
Other Considerations
High Throughput Exposomics

NIH Genes, Environment and Health Initiative
Exposure Biology Program

Genes, Environment and Health Initiative: The Vision

EXPOSURE BIOLOGY PROGRAM
- Develop technology and biomarkers
  - Diet
  - Physical Activity
  - Environmental Exposures
  - Psychosocial Stress and Addictive Substances

GENETICS PROGRAM
- Identify genetic variants
  - GWA Studies
  - Data Analysis
  - Replication
  - Sequencing
- Database
- Function
- Translation

GxE
“Unlike the genome, the exposome is a highly variable and dynamic entity that evolves throughout the lifetime of the individual...”

-- Christopher Paul Wild
Together these lead to whether disease occurs or health is promoted...

Kevin Patrick, UCSD, NCI U01 CA130771
Do it right or lose them

I think we can safely assume the promise of apps radically revolutionizing our health is heavily inflated. So, then, what good are health apps? Health apps are the equivalent of old school public health advertising. Just as I see an ad when I get on the subway telling me this soft drink has 40 packets of sugar, I whip out my iPhone and see the Livestrong app on my homescreen reminding me that I need to eat well. I don’t really want to use it because it’s such a drag.”

Jay Parkinson of Future Well, 2011
Moving “Hype” to Productivity

mHealth Hype Cycle

- Peak of Inflated Expectations
- Trough of Disillusionment
- Plateau of Productivity
- Slope of Enlightenment
- Technology Trigger

TIME
Challenges

Building a Sustainable Future for Mobile Behavioral Health Research
Research/Funding Challenges

- Technology development (rapid) versus NIH funding process (slow) timelines.
- Interdisciplinary research teams needed versus traditional academic model.
- Research methodology for data collection/analysis.
- NIH study sections – grant reviewers.
- IRBs/HIPAA.
- Getting to know who to talk to at NIH
Current Evidence on mHealth

- Only 20 RCTs evaluating mHealth could be found in the peer reviewed literature (2008-2012).
- Of the 20 trials
  - 11 (55%) failed to document a clear benefit of the mHealth intervention
  - 3 (15%) had a mixture of positive and null results
  - 6 (30%) showed clear benefit

Problems With Current Literature

• Most of the published studies:
  ▫ Include few people, who may or may not be like the people who will eventually use it
• Few of the studies were registered in ClinicalTrials.gov, which means that if they have no positive results they may never be published
• Too few teams in this area have the skills needed to utilize the technology in a way that can engage people in a reliable and valid manner
Workshop on mHealth Evidence

- Collaboration between Robert Wood Johnson, McKesson foundation, NSF and NIH
- Workshop in August 2011 at NIH to assess mHealth study design and analytic possibilities
- This presentation stems from the workshop
- Special thanks to: Santosh Kumar, Kevin Patrick, Bill Riley, Misha Pavel and Al Shar, as well as many others who worked together to develop an evidence generation plan.
Diagnostics and Assessment Tools

**Reliability:** Consistency of a measure.
- Test-retest: Are values repeated over time?
- Inter-method: Do methods show agreement?

**Validity:** Degree a measure assesses what it claims
- Construct:
  - Does it have similar values with other measures assessing the same thing?
  - How does it compare to the “gold standard”?
  - Does it’s values differ from measures of other constructs?
  - Does it predict what it should?
Randomized-Control Trials

Let’s not throw the baby out with the bath water.
Next Steps

- We do have designs that will support mHealth evaluation. **BUT**, mHealth may actually make the standard designs more efficient
  - Extensive measurement
  - Ability to do predictive modeling
  - Real-time analytics
  - Encourage treatment adherence
  - Non-invasive measures may decrease burden
  - Remote intervention may enhance recruitment
- The RCT pace & expense may be better in mHealth.
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
Future Areas of Research

- Continuous Evaluation of Evolving Interventions (CEEI)
  - New versions in CEEI are deployed along with the previous version, with users randomized to available versions. The most efficacious version, based upon a priori criteria, is retained.

- Data Mining and Modeling
  - Creating personal signatures that can be predictive and reduce time to outcomes

- Open mobile architecture (e.g., Open mHealth)
  - Build on existing successes rather than one-offing
Current NIH Research Support

- **PA-11-330** mHealth Tools to Promote Effective Patient Provider Communication, Adherence to Treatment and Self Management of Chronic Diseases In Underserved Populations (R01, R21, R03)
- **PAR-11-020** Technologies for Healthy Independent Living (R01, R21)
- **PA-10-122** SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries [SBIR: R43/R44]
- **PA-11-118** HIV/AIDS Testing and Follow-up Among the Underserved in the United States (R01)
- **PA-11-063** Translating Basic Behavioral and Social Science Discoveries into Interventions to Improve Health-Related Behaviors
- **May be more that include mobile, but not target it directly**
2013 NIH mHealth Training Institutes

- **Need**
  - Improved use of mHealth products in clinical and behavioral research
  - Increased collaboration and cross-fertilization across disciplines

- **Plan**
  - 5-day training for 42 participants
  - Develop skills to improve the design and research of mobile technologies
  - August 26030, 2013 University of California, Los Angeles
Join our Listserv

- **mHealth-Training@list.nih.gov**
  Join the electronic mailing list (LISTSERV) for forthcoming announcements by —
  Sending an e-mail message to listserv@list.nih.gov from the mailing address at
  which you want to receive announcements.

  The **body of the message** should read *SUBscribe mHealth-Training [your full name]*.

  The message is case sensitive; so capitalize as indicated!
  - Don't include the brackets.
  - The Subject line should be blank
  - For example, for Robin Smith to subscribe, the message would read
    *SUBscribe mHealth-Training Robin Smith.*

  You will receive a confirmation of your subscription along with instructions on
  using the listserv.
Thank you!

- Thank you!
  - Wendy Nilsen, NIH Office of Behavioral and Social Sciences Research
  - 301-496-0979
  - nilsenwj@od.nih.gov