Welcome

Opportunities and Challenges in mHealth Applications
Mobile Monday DC

Speakers
Todd A. Radano
William Riley, Ph.D.
Glenn Roland

Moderator
Stephanie A. Joyce

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Smart in your world®
Arent Fox
William Riley, Ph.D.
Chief, Science of Research and Technology Branch
Division of Cancer Control and Population Sciences
National Cancer Institute

- SRTB Scientific Priorities
  - Theory development, testing and application;
  - Measure development and testing;
  - Technology development and application;
  - Methodological innovation, particularly in analytic approaches;
  - Data harmonization and research synthesis; and
  - Team science and cross-disciplinary approaches.

- Co-Chair, NIH mHealth Interest Group (mPower)

- mHealth Summit Planning Committee – Research Track (Dec. 8-11)
mHealth Related Publications

Health behavior models in the age of mobile interventions: are our theories up to the task?
William T Riley, PhD, Daniel E Rivera, PhD, Audie A Adonza, PhD, Wendy Nilson, PhD, Susannah M Allison, PhD, Robin Mermelstein, PhD

Mobile phone-based smoking cessation interventions increase long-term quit rates compared with control programmes, but effects of the interventions are heterogeneous
William Riley and Erik M Augustson
Evid Based Nurs 2013 16: 108-109 originally published online February 6, 2013
doi: 10.1136/eb-2012-101204

Leveraging Technology for Multiple Risk Factor Interventions

Health risk behavior change research has focused predominantly on a single risk factor, but most of the general population (50%) has 2 or more chronic disease risk factors. Interventions that target multiple risk factors should improve the prevention of disease better than single risk factor interventions, but systematic reviews of multiple risk factor interventions have produced disappointing results. In this issue of the Archives, Spring et al1 provide examples of 2 innovative research directions that have the potential to improve outcomes in multiple risk factor intervention research.

Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise
William T Riley1, Russell E Glasgow1, Lynn Etheredge2 and Amy P Abernethy2
mHealth Devices before “mHealth”
OPPORTUNITIES AND CHALLENGES IN MHEALTH
A MOBILE MONDAYS PANEL DISCUSSION
SEPTEMBER - 2013

Panel Participant: Glenn Roland
The Dominion Group Market Research and Consulting
Todd Radano
President

1010 Wisconsin Ave NW, Suite 310
Washington, DC 20007
www.decisionq.com
DecisionQ Overview

- Over 15 years of research and development into the most scalable machine learning platform in the industry
- Partner oriented business model with a focus on solving complex, difficult problems
- Extremely experienced modeling and analytical staff
- Over 45 peer-reviewed publications with acknowledged thought leadership
- Extensive IP portfolio
“mHealth (also written as m-health or mobile health) is a term used for the practice of medicine and public health, supported by mobile devices. The term is most commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, for services and information, but also to affect emotional states.”

- Wikipedia

“Over time, the market for the technology has become so broad that many use the terms Mhealth, Mobile Health, Digital Health, etc. interchangeably......”
Technology was not robust enough, the physical characteristics of mobile devices were limiting...so past interactions relied heavily on text messaging......and, that wasn’t very compelling.

Healthcare Reform and the Need to Lower Costs
The move toward digital content and improved access to healthcare data....

Exponential Growth in the number of Global mobile subscribers
6.8 billion at the end of 2012 (ITU)

“Advances in Mobile device Characteristics”
56% of doctors now use smartphones

Active instead of “reactive” healthcare....and a continuing trend toward patient empowerment”
31% Or 1 in 3 of cell phone owners have used their phones to look for health information. 2 years ago that percentage was 17%.

52% of smartphone owners gather health information on their phones
## The Opportunity – Digital Health Investment

### Top Investment Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Fitness</td>
<td>Apps used for health and fitness</td>
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<tr>
<td>Education</td>
<td>Inform patients and act as reference for physicians</td>
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<td>Reminders</td>
<td>Appointment scheduling, medication alerts</td>
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<td>Research</td>
<td>“In the moment” interactions with patients</td>
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<td>Communication</td>
<td>Used to enhance physician patient interactions and compliance</td>
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<td>Enterprise</td>
<td>Mobile extensions to enterprise systems</td>
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<tr>
<td>Referrals</td>
<td>Used by patients to find docs</td>
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<tr>
<td>Diagnostics</td>
<td>Apps intended to diagnose specific illness</td>
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</tbody>
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**“Mobile health app marketplace to take off, expected to reach $26B by 2017”** - Mobile Marketer

### Venture Funding for Digital Health

**Remains Strong**

(cumulative funding in millions)

<table>
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<th>Year</th>
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Source: Rockhealth
Diagnostic Advances via Pattern Recognition

Innovative Advances in “Input”

User

Implantable Biosensors
Burgess, R21HL090458
Innovative Advances in “Input”

User

Inputs

Wearable, Waterproof
Accelerometers
Intille, U01HL091737
Innovative Advances in “Input”

User

Personal Chemical Exposure Sensors
Tao, U01 ES016064
Innovative Advances in “Input”

Wireless Salivary Biosensors
Shetty, U01DA023815
Innovative Advances in “Input”

Inputs

User

Miniature Microscope
Ozcan, R21EB009222
But Where’s the Output?

Inputs

User

Integration & Analytics

?
CHALLENGE - FDA OVERSIGHT

FDA definition:...an instrument, apparatus, implement, machine, contrivance, implant, or in vitro that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any other function of the body......

“Final guidance will clarify selective enforcement but unlikely to change overall oversight approach...”

Source: FDA.gov
Today the FDA released “Mobile Medical Applications: Guidance for Industry and FDA Staff” (see Client Alert at www.arentfox.com)

- “[S]hould be viewed only as recommendations” and does not “establish legally enforceable responsibilities[.]”
- Core principle: risk to consumers’ health in the event of malfunction
  - Unlikely to investigate apps that simply organize EHR and information about prescribed treatments or that automate tasks for a health care provider
  - Likely to investigate apps that enable a health care provider to make specific diagnoses and apps that turn PDA into an electrocardiography device

*Is it merely organizing information or is it rendering/enabling specific diagnoses?*
Guidelines Continue to Develop

• New Report expected January 2014, as “a start of the process”; will seek additional comment
• FTC and FCC retain respective jurisdictions over telecom, consumer protection, and competition law
• FDA has established an email account to field questions about the Guidelines:
  MobileMedicalApps@fda.hhs.gov
CHALLENGE - PATENT-ASSERTION ENTITIES

...patent assertion entities (also called patent trolls) do not manufacture goods themselves but profit from licensing agreements that they often enforce via the threat of litigation......

- PatentFreedom.

"Dumbass patents are crushing small business" – Mark Cuban

Although legislation (Leahy-Smith America Invents Act (AIA)) was enacted in 2011 to curb the activities of these entities, they still pose a significant risk to the emerging market for innovation in the Digital Health/MHealth space.
I’m always interested in connecting with like-minded professionals on Linked IN. I’m not that big on tweeting, my life isn’t that interesting.
Technology Outpaces RCTs

- YouTube (2005)
- iPhone (2006)
- Android (2007)
- iPad (2008)
- 2009
- 2010
- 2011

- Grant Submit and Award
- Development and Pilot Testing
- Recruit and Randomize
- Follow-ups
- Analyze and Publish
Thank You For Joining Us

• Next MoMo: October 7, 2013
  Data and Analytics Go Mobile
  http://dcmomo.com

• Ask about the HIMSS mHealth Summit
  December 8-11, 2013, and find out how to
  receive the Arent Fox discount