mHealth: Can it Transform Care and Clinical Trials?

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- I serve as a medical advisor for Agile Edge Health, DynoSense, Airstrip and FocusMotion, and Chief Medical Advisor and Board member for Vantage MobileHealthcare.
What is mHealth?

“mHealth (or mobile health) is the use of mobile or wireless devices to improve health outcomes, healthcare services and health research.”

- NIH Consensus group
“When we talk about mobile health, we are talking about taking the biggest technology breakthrough of our time and using it to take on one of the greatest national challenges of our time.”

Kathleen Sebelius, Former US Secretary of HHS
mHealth Summit December 2011
Gartner's 2014 Hype Cycle for All Emerging Technologies

http://www.gartner.com/newsroom/id/2819918
mHealth: Can it Transform Care and Clinical Trials?

1. Starting the (technology) revolution without us.
2. Where can mHealth make a difference?
3. Enter the interlopers.
4. Barriers to transformation.
5. Clinical trial examples
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ASCI Red

- World’s fastest super-computer in 1996 – 1.8 teraflops/sec (1.8 trillion operations /sec)
- $55 million to develop.
- Occupied 1,600 square feet of floor space.
- Used 800 KW/hr (~800 homes)

- 2006 – 1.8 teraflops/sec
- $500
- 200 watts
- 64 million units sold
May, 1997

IBM’s Deep Blue beat World Chess Champion Garry Kasparov.
Watson is now “…the size of three pizza boxes stacked up. It's also 24 times faster and has seen a 2,400 percent improvement in performance.”
In the US, 91% of adults own a mobile phone, with the majority of them (61%) being smartphones.

194 minutes a day looking at smartphone or tablet screen. 147 looking at TV, 103 at laptop or PC.

Projected Worldwide Growth in Mobile & Smartphones

Smartphones, mobile PCs, tablets and mobile routers with cellular connection

300 million mobile PCs, tablets and mobile router subscriptions
1.9 billion smartphone subscriptions

700 million mobile PCs, tablets and mobile router subscriptions

5.6 BILLION smartphone subscriptions by the end of 2019

- Orange bars: Mobile PCs, tablets and mobile router subscriptions
- Red bars: Smartphone subscriptions

Ericsson Mobility Report June 2014
A Historical (and Present Day) Look at Our Tools for a Patient’s Office Visit

Blood Pressure

- Sphygmomanometer invented 1881.
- Popularized by Harvey Cushing 1901

ECG

- Willem Einthoven 1901.
- Precordial leads introduced 1944

Physical Exam/Auscultation

- Laënnec 1816.
- Binaural stethoscope 1851

House Calls

- In 1930’s ~40% of all patient encounters were in their home.

Unwin BK. Am Fam Physician 2011
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Today’s Most Commonly Collected Wearable Sensor Data
(Owned by ~1-in-10 adults in US)

1. Activity
2. +/- Sleep
3. +/- Pulse
The Near Future of Wearable Sensor Data

1. Activity
2. Pulse
3. Sleep stages
4. Blood pressure
6. ECG
7. Stress
   - HRV
   - EDA
8. Respiration rate
9. Oxygen saturation
10. CO2 levels
11. Temperature
12. Hydration
13. Glucose (?)
**Eye / Ear**
- Smart Hearing Aids
- Contact lens-based glucose sensing
- Digital otoscope / fundoscope
- Noninvasive Intraocular pressure
- Automated refractive error
- Smartphone visual acuity tracking

**Brain / Emotion**
- Wireless, mobile EEG
- Head impact sensing
- Noninvasive intracranial pressure monitor
- Autonomic nervous system activity
- Stress recognition via voice / respirations
- Seizure detection

**Heart / Vascular**
- Continuous & intermittent rhythm monitors
- Noninvasive continuous BP tracking
- Cardiac output/stroke volume
- Thoracic impedance (fluid status)
- Handheld echocardiography

**Stomach / Intestine**
- Esophageal pH sensing
- Endoscopic image transmission
- Medication compliance sensors
- Fecal blood / bilirubin detection
- Gut electrical activity sensing
- Chewing monitor

**Blood**
- Continuous glucose
- Point-of-care blood tests
- Transdermal hemoglobin
- Genomics-based pathogen identification

**Urine / Bladder**
- Comprehensive urinalysis
- Genomic identification of STDs
- Diaper-based sensors

**Skin**
- Skin temperature
- Gross lesion assessment
- Pressure sensing for wound care
- Sweat chemistry
- Electrodermal activity
- Cutaneous blood flow

**Lung**
- Home Spirometry
- Continuous pulse oximetry
- Inhaler Utilization
- Breath-based diagnostics
- Breath sound detection
- Environmental exposures identification

**Miscellaneous**
- Pill-box & bottle sensors
- Fetal monitoring
- Posture / Position sensors
- Activity monitors
- Sleep trackers
“You’ve got to start with the customer experience and work back toward the technology - not the other way around.”

Steve Jobs
1955-2011
Hypertension (High Blood Pressure)

1. One of every 3 adults in America has high BP.
2. Nearly $100 billion in total costs are attributed to high BP annually in the US.
3. Nearly 40 million office visits every year in the US have a primary diagnosis of hypertension making it the single most common reason for an office visit.
4. Less than half of all individuals in the US, and 20% worldwide have their blood pressure under control.

Improving HTN Management Through mHealth

- Home BP monitoring alone is already known to improve BP control, although only slightly (~2mmHg).
- When home monitoring is coupled with self titration of blood pressure medications proved to be significantly more effective than physician care in 2 studies.

Simplified and Connected HTN Management

• Cuffless and continuous non-invasive BP monitoring devices will soon allow for a substantially greater depth of understanding of BP and its control.
Diabetes Management Today

1. ~11.9% of the adult population has diabetes, with ~3% being undiagnosed. ¹

2. An additional ~79 million are pre-diabetic. ¹

3. 37.3 million ambulatory care visits occur annually with a primary diagnosis of diabetes. ¹

4. The total cost of diabetes in the US for 2012 was $245 billion, with $176 billion in direct costs. ²

The Next Generation of Continuous Glucose Monitoring

Bandodkar AJ. Anal Chem 2015;87:394-98
Heart Failure

- More than 5 million Americans are diagnosed with HF; expected to climb to 8 million by 2030.
- Leading cause of hospitalization for Medicare beneficiaries.
- Annual costs of $31 billion expected to increase to $70 billion by 2030.
- Following a HF admission 50% will be readmitted within 6 months.

Schocken DD. Circulation 2008;117:2544-65
Heidenreich PA. Circulation. 2011;123:933-944
Desai AS. Circulation. 2012; 126: 501-506
mHealth Heart Failure Management
Real-Time Biometric Data from Wearable Sensors

Charts view of analytics for heart rate and pulse transit time
Nonparametric Model-Based Analytics Personalized to Each Individual

- Enrolled Dec 5
- SBM Multivariate Health Index Concatenated Days with Data
- Hospital Admission Dec 26 (Day 21)
- Call to Patient: “I don’t feel any different”
### Healthcare Team

- Physician
- Nurse
- Pharmacist
- Dietician
- Physical Therapist
- IT

### Personalized Predictive Analytics

Automated Clinical Decision Support

Learning Healthcare System

*Image of a table showing medication adherence.*
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“How many businesses do you know that want to cut their revenue in half? That’s why the healthcare system won’t change the healthcare system.”

Rick Scott
Florida Governor
Founder of Columbia Hosp Corp, then CEO of Columbia/HCA, the largest private for-profit health care company in the U.S
“The $2.8 trillion US healthcare industry is being upended by companies attuned to the needs and desires of empowered consumers.”

pwc. Health Research Institute April 2014. Healthcare’s new entrants: Who will be the industry’s Amazon.com?
“Are you open to trying new, non-traditional ways of seeking medical attention and treatment?”

83% of consumers would be open to new, non-traditional forms of medical care.

Source: HRI consumer survey, December 2013

pwc. Health Research Institute April 2014. Healthcare’s new entrants: Who will be the industry’s Amazon.com?
Yearly Growth in Annual Out-of-Pocket Healthcare Spending

Truven Healthcare Spending Index December 2014
Consumer and Clinician Willingness to Adopt Home Testing

- Consumers likely to choose DIY over traditional option:
  - Use an at-home strep test at a store: 58%
  - Check vital signs at home with device on phone: 55%
  - Send digital photo of skin problem to dermatologist: 54%
  - Check for ear infection using device on phone: 47%
  - Have ECG at home using device attached to phone: 44%
  - Do urinalysis test at home with device on phone: 42%

- Clinicians comfortable relying on DIY diagnostic tests to prescribe medication:
  - 43%
  - 53%
  - 48%
  - 26%
  - 32%
  - 47%

PWC 2014. Healthcare Delivery of the Future
• 900 locations in 29 states
• Staffed by nurse practitioners and physician assistants
• 21 million patient visits
• Healthcare Clinic locations across US
• Already collecting mHealth data remotely in 81
  million for Balanced Rewards loyalty program.
• Exclusive partnership with Theranos for in store
  lab testing.
Willingness to Have a Video Doctor’s Visit

Harris Poll Survey of 2,019 adults in December 2014

Teladoc+
Video consultation for Jane Smith

Write Tips
Frequently Asked Questions

Beware of the “gain” angle. Maintain eye contact.
Just like in person, it is important to look up at the camera to maintain eye contact with the person you are speaking with.

Turn on the lights.
Wear proper clothing.
Slow down.

Call a Licensed MD to Schedule Online.
- Schedule Your Call
- Ask Questions
- Pay
- Submit

CALL NOW
SEVENTYFIVE
2AZBVMN
CANCEL

Dr. DOCTOR

DermatologistOnCall®
PHOTOS
Diagnosis Pending 09/11/2013

Back Arm Hand Right
Back Leg Lower Left

Replace?
Replace?
Replace?

Neck Left

Replace?
Upload Photo

Home
Log Out

Book a Doctor

100 Morton St
New York NY 10014

Pager
Available in Manhattan
From 6pm to 12am
Google trial lets you chat with doctors when you search for symptoms

by Jon Fingas | @jonfingas | October 11th 2014 at 11:59 pm

Why Facebook Could Become the World's Biggest Healthcare Network

Facebook (NASDAQ: FB) could soon follow Apple (NASDAQ: AAPL), Samsung (NASDAQOTH: SSNLF), and Google (NASDAQ: GOOG, GOOGL) into the healthcare field. According to a recent Reuters report, the company is experimenting with online support communities for patients and mulling the development of personal health and fitness apps.
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Healthcare Providers: Much Room for Improvement in Professional Satisfaction

1. In general, physicians are unsatisfied with their careers:¹
   - Morale considered poor to very poor by 80% of physicians.
   - Two-thirds would not recommend it to younger individuals
   - One-third, if given the chance, would no longer choose to be a physician.

2. ~80% of physicians rate the doctor-patient relationship to be the most satisfying aspect of their work.¹ However,
   - Today, average face-to-face time with a patient is ~10 minutes²
   - It would take between 11-18 hours daily for a PCP to provide just the preventative and chronic disease management required for a typical patient compliment.³,⁴

Information Explosion in Medicine

- Currently > 18 million articles indexed in the biomedical literature.
- The accession rate has doubles in last 20 years with ~ 1 million new articles indexed in 2012.
- To read everything of potential importance PCP would need to read ~7,287 articles a month. Assuming ~2 minutes/article would require 11.7 hours/day.
- 75% of physicians admit to having trouble understanding statistics in publications.

The Best Care at Lower Cost Institute of Medicine 2012
Lundberg GD. Bull Med Libs Assoc 1992;80:110-4
Alper BS. J Med Libr Assoc 2004;92:429-37
Cranney M. Br J Gen Pract 1996;46:661-3
“...high quality adequately powered trials of optimised interventions are required to evaluate effects on objective outcomes.”

“The paucity of evidence calls for much needed future research...”

“High quality trials measuring clinical outcomes are needed.”
Incorporation of mHealth into Existing Systems of Care

Systems of care need to be re-engineered around the capabilities that mHealth tools provide.

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Growth in Clinical Trials in Digital Medicine
Transforming Management of the HF Patient - CoVa™ Sensor

- **Measurements:** thoracic fluids, heart rate, HRV, respiration rate, skin temperature, posture, ECG.
- **Prototype:** SpO2, blood pressure, stroke volume, cardiac output.
Transforming the Diagnosis and Management of Sleep Apnea

MultiSense™

- Single-lead ECG
- Heart rate & variability
- Oxygen saturation
- Respiratory rate & depth
- Activity
Wearable Sensors for Identifying Physiologic Biomarkers of PTSD Treatment Response

Monitoring for 48 hours at start, middle and end of a 10 week residential treatment program for PTSD utilizing an array of Cognitive Behavioral Therapies.
100,000 with increased risk of AF as determined through claims data invited to participate

~2,000 agree to participate and sign ICD

1000 Immediate Monitoring

No Monitoring – Routine care

1000 Delayed Monitoring (No monitoring – Routine care)

1000 Begin Delayed Monitoring

From the ~98,000 who decline participation or do not respond 4000 randomly selected age, gender and co-morbidity-matched controls are identified.

~2,000 Active Monitored Cohort

Primary Endpoint
Incidence of newly diagnosed AF as defined by at least 30 seconds of AF or atrial flutter at the end of the 6 month monitoring period compared to the delayed monitoring cohort (primary) and observational control (secondary).

6 months

Key Secondary Endpoint
1. Prevalence of atrial fibrillation in monitored vs control.
   a. Rate of initiation of anticoagulant therapy in active cohort versus control.
   b. Difference in healthcare utilization/costs.

1 Year

15 months

Key Secondary Endpoint
1. Time to first event of stroke, systematic emboli and MI in patients diagnosed with AF at year 3 in the monitored vs. control cohorts.
2. Difference in total healthcare costs in AF cohorts of monitored and controls.

3 Years

mSToPS
mHealth Screening To Prevent Strokes

iRhythm Zio patch worn for first and last 2 weeks of 6 month monitoring period.

Amiigo wristband worn daily in subset of the monitored cohort.
Retinopathy Assessment and Follow-Up at Home

Web-based recruitment of up to 1000 individuals with:
- Diabetic Macular Edema, or
- Age-Related Macular Degeneration
- Tx with Lucentis
- Own a iOS device

Home vision testing ~2x/week for 6 months.

Data input from volunteers’ ophthalmologist.

- Three circles – touch the one that is different

myVision Track™
Sensor Technology to Assure Medical Provider Safety (STAMPS)
A User-Centric Approach to Developing Innovative Blood Pressure Management Technology for Use in a Low-Resource Setting
mHealth: Can it Transform Care and Clinical Trials? - Summary

• We are in the midst of a technology revolution of unprecedented computational power and continuous connectivity that has so far not been taken advantage of in healthcare.

• mHealth technologies can facilitate, but only can not drive the complete re-engineering of healthcare that better engages and empowers consumers, improve outcomes, lower costs, and improve satisfaction for all involved.

• Transformation of healthcare is being driven by multiple non-traditional, consumer-centric corporations.

• The evidence to drive this transformation is currently limited but that can be rapidly changed through thoughtful implementation with surveillance, adaption & dissemination.