What’s Next: People-Powered Knowledge Generation from Digital Health Data
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Speaker Introduction

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Conflict of Interest

Harlan M. Krumholz, MD
Salary: Yale University; Yale New Haven Health
Consulting Fees: UnitedHealthcare, IBM Watson Health, Element Science, PCORI
Contracted Research/Deliverables: CMS, FDA, NIH, AHRQ, Johnson and Johnson, Medtronic, American College of Cardiology, Blue Cross Blue Shield, State of Connecticut
Other: Hugo (personal health information platform)

Lin Wan, PhD
Salary: Stella Technology, Inc.
Agenda

- Problem Statement
- Government Initiatives
- Features of a Solution
- Questions
Learning Objectives

• Describe how greater availability of digital health data provides opportunities to improve research enterprise

• Show examples of how federal efforts are promoting participant engagement through Sync-for-Science

• Describe opportunities of these research directions
Platforms like Hugo provide a user-friendly application to patients and enables them to:

- Maintain a comprehensive/consolidated health record that’s easy to understand
- Take control of their own health record for different purposes
- Become an integral/active participant in care and research activities
Problem Statement

The current knowledge generation enterprise is inadequate to keep up with the information needs of patients, clinicians, health systems, regulators, and others.
The answer unlikely to be more $$

US Funding for Medical Research by Source, 1994-2012
Inefficiencies

Screening
Enrollment
Retention
Follow-up
Sisyphus by Titian

…or the experience of doing clinical research.

Another Issue: Time
Cardiovascular Safety of Celecoxib, Naproxen, or Ibuprofen for Arthritis

Steven E. Nissen, M.D., Neville D. Yeomans, M.D., Daniel H. Solomon, M.D., M.P.H., Thomas F. Lüscher, M.D., Peter Libby, M.D., M. Elaine Husni, M.D., David Y. Graham, M.D., Jeffrey S. Borer, M.D., Lisa M. Wisniewski, R.N., Katherine E. Wolski, M.P.H., Qiuqing Wang, M.S., Venu Menon, M.D., Frank Ruschitzka, M.D., Michael Gaffney, Ph.D., Bruce Beckerman, M.D., Manuela F. Berger, M.D., Weihang Bao, Ph.D., and A. Michael Lincoff, M.D., for the PRECISION Trial Investigators*
Can we break through the constraints?

\[
\begin{align*}
\text{Better} \land \text{Faster} & \rightarrow \neg \text{Cheaper} \\
\text{Faster} \land \text{Cheaper} & \rightarrow \neg \text{Better} \\
\text{Cheaper} \land \text{Better} & \rightarrow \neg \text{Faster}
\end{align*}
\]
The Basic Idea

People as partners instead of subjects can unleash the means to achieve better, faster, cheaper research.
EHR Adoption

- **Certified EHR**
  - 2008: 9.4%
  - 2009: 12.2%
  - 2010: 15.6%
  - 2011: 71.9%
  - 2012: 85.2%
  - 2013: 94%
  - 2014: 96.9%
  - 2015: 96%

- **Basic EHR**
  - 2008: 59.4%
  - 2009: 44.4%
  - 2010: 27.6%
  - 2011: 75.5%
  - 2012: 83.8%

Participants want not only to be invited to the table but also to design and host the meal with other stakeholders.
Time is Right

From passengers to co-pilots: Patient roles expand

Margaret Anderson* and K. Kimberly McElroy*

The promise of medical research on the US national policy agenda offer an unprecedented opportunity to advance the science of patient input and make a turning point in the evolution of patient engagement.

For most of history, patients have been the passengers, sometimes even the subjects, of medical research. In today’s world, patients have become more involved and engaged in the process of medical research and development. This is due in part to the implementation of laws and regulations that encourage patient involvement in the research process. The Patient Protection and Affordable Care Act of 2010, for example, requires that patient input be considered in the development of new medical products and treatments.

However, the role of patients in medical research has not always been a positive one. In the past, patients were often excluded from participating in research, and when they were included, their input was often ignored. This is changing, and the role of patients in medical research is becoming more prominent.

Patient engagement offers the promise of advancing more personal and efficacious medical products faster than the typical ~15-year discovery-to-market timeline.

The promise of medical research on the US national policy agenda offer an unprecedented opportunity to advance the science of patient input and make a turning point in the evolution of patient engagement.
Time is Right

Power to the People: Participant Ownership of Clinical Trial Data

Sharon F. Terry* and Patrick F. Terry

Participation in clinical trials is a dimly lit cause. In this age of electronic sharing of information, all sorts of trial participants can easily obtain clinical trial data. The benefits of participant ownership and sharing of trial data appear to outweigh the risks. Thus the time has come to create a novel data for diagnostic and therapy development.

COMMONS CONCEPT IN THE CLINIC

"To think that many academic researchers..." says J. B. Hunter, a heath-galvanizing... (full text cut off)

This notion is one that should be embraced throughout every community of patients, scientists, and policy makers. Why can't those who contribute data to clinical studies—the participants—decide when the data will make and who will be able to use it? What if the commons concept—instead of various kinds of ownership collectively—are applied to clinical trial data? There is a dynamic interface for data sharing (Fig. 12). Would we be able to have new workflows for a devolution sparked by laws?

In the present time, clinical trial data reside with the sponsor of the trial, which is usually a company or an academic institution. A great deal has been written about the future of the clinical trial return to a community system (24). However, discussions about changes in data ownership policies are occurring, and some experiments are underway where data control has shifted to the person providing the data. The ability to access data—especially clinical trial data—is a critical component of the potential availability of electronic medical records (EMR) and personal health records (PHR). It stands to reason that clinical trial data will become liquid as well.

SHARING: MORE THAN GOOD MANNERS

Why should clinical trial participants share data? A trial's success might be indebted to the open sharing of data. The age of Facebook and Twitter, individuals share a great deal of information much more easily and willingly than in prior times; some people might be inclined to share clinical trial data as well. However, this means crossing the impossible boundary two times.

Many individuals who are engaged in clinical trials today areEpstein brought a very nice-... (full text cut off)

LUMINATIONS INCENTIVE SHARING

For any diagnostic test or therapy to be approved, human trials must be conducted. However, few individuals engage in trials, and 30% of clinical trial sites enroll one or no patients in their trial (18). A ma... (full text cut off)

[Fig. 1. "What's my data is mine and what's your data is also mine."—Sydney Brenner, on data-sharing (18).]
“Second opinions matter. Information prevents redoing.” —Kathryn B., California

Get the information you need to better manage your health, or care for loved ones. With online access and communication tools, patients can ask questions, share concerns, and provide pertinent information to their providers at their convenience – at night, over the weekend, even on a holiday.

Learn WHY You Should Request Your Health Data

http://getmyhealthdata.org
“Tonight I’m launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes.

And to give us all access to the personalized information we need to keep ourselves and our families healthier.”

President Barack Obama
2015 State of the Union Address | January 20, 2015
Recommendation 5.10: PMI should support development and evaluation of tools that enable individuals to acquire, transmit, and continuously update their EHR data to the PMI cohort from multiple provider organizations.
NIH and ONC announce Sync for Science to enable patients to donate data to Precision Medicine Initiative

EHR makers including Allscripts, athenahealth, Cerner, drchrono, Epic and McKesson said they will embrace open specs including S4S APIs and FHIR to connect research apps to electronic health records software.
CONSUMER-MEDIATED EXCHANGE
Consumer-mediated exchange provides patients with access to their health information, allowing them to manage their health care online in a similar fashion to how they might manage their finances through online banking. When in control of their own health information, patients can actively participate in their care coordination by:

- Providing other providers with their health information
- Identifying and correcting wrong or missing health information
- Identifying and correcting incorrect billing information
- Tracking and monitoring their own health
- Learning more about the benefits of consumer-mediated exchange.
• Develop methods to facilitate individually-controlled clinical data donations to the PMI Cohort.

• Accelerate and guide the national ecosystem for patient-mediated data access through APIs.

I believe that the most important requirement for the new knowledge network envisaged by the “Precision Medicine” report is that it be driven by patients.
Cancer Moonshot
Recommendation D:

A National Cancer Data Ecosystem for Sharing and Analysis
The enormous volume of data being generated by cancer researchers, clinicians and patients today requires a national infrastructure to share, combine and analyze those data in an easy-to-access format.

Central tenet of National Cancer Data Ecosystem is enabling the public, including all cancer patients and others, to directly contribute their data, or to request a healthcare provider do so on their behalf, for scientific research.

Patients are interested in contributing their views, data, and resources to increase early access to high quality, safe and effective medical devices, reduce adverse events, and improve communication about the risks and benefits that matter most to them.

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHPatientEngagement/default.htm
Time for a Patient-Driven Health Information Economy?

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D.

As patients strive to manage their own health and illnesses, many wonder how to get a copy of their health data to share with their physicians, load into apps, donate to researchers, link to their genomic data, or have on hand just in case. To seek diagnosis or better care (see table), many patients are taking steps outside traditional doctor–patient relationships. Some join 23andMe to obtain genetic information. Others bring data to the Undiagnosed Diseases Network at the National Institutes of Health (NIH). Patients are coalescing with others with the same disease in what the Patient Centered Outcomes Research Institute calls patient-powered research networks. But such patients have found no easy way to get copies of their electronic health records (EHRs).

In 1994, when the World Wide Web was only 2 years old, Massachusetts Institute of Technology computer scientist Peter Szolovits, presaging the consumer health information technology (IT) movement, proposed, in the Guardian Angel Project, using the Web for patient management of health and health data. Yet getting patients electronic copies of their health records has remained an elusive goal. Industry giants have scars to show for their attempts. Why have the barriers been so high? And what is the path to a patient-driven health information economy?

In 1998, we developed the Personal Internetworked Notary and Guardian (PING, later called Indivo), an NIH-funded system for automatically and continuously updating a patient-controlled data repository. Indivo downloaded Patients were invited to use portals at all their providers’ practices (a solution that caused a condition sometimes called “hyperportalosis”).
Dear John: *I* want to download my records.

Dear Dr. Halamka,

I want to download all my data from my 14 years as a patient at Beth Israel Deaconess Medical Center. What button should I push?

In June you said on your blog (left, top) and on MedCity News that no patient has ever asked for that, but your tech support says you don’t have a way to do it (see red outline).

Tech Support said I should call Medical Records. I did, and they said they can’t deliver things electronically. So where is the link you say nobody has ever used?
Impediment

Business models that depend on data as proprietary assets.
Solution must protect privacy and security while enabling each person’s access to his or her health-related data and providing opportunities to leverage them.
Approach

- People first
- Frictionless data flow
- Excellence in UI/UX
- Stringent privacy policies and security
- Minimize dependence on data holders
Disruptions

Screening
Enrollment
Retention
Follow-up

…Knowledge generation
Accessing and obtaining copies of one’s health information for one’s own purpose is a right, not a privilege which is fundamental to your ability to participate in our health care system.

The right extends to a broad array of information (i.e., lab results, images, prescriptions, notes), as well as to data holders (i.e., doctors, hospitals, health plans and providers)

Per page charges do not apply when the individual is requesting a copy of information maintained electronically.

Technology – Secure and Comprehensive

Secure, scalable, cloud-based platform
• Horizontal scalability designed to support consumer application
• Highly automated for ease of operation
• Extensive PHI security (encryption, access control, auditing…)

Comprehensive & extensible data platform
• NOSQL database with FHIR-like extensible data model
• Well-defined API layer for ease of integration and extensibility
A Flexible and Standards-Based Platform

Application (Web/Mobile)

Security (SAML, OAuth, UMA, etc.)

Data Intake
- Validate
- Standardize
- Aggregate

Connectivity/Interoperability: Messaging and Data
- Blue Button
- IHE/eHealth Exchange
- FHIR
- Direct
- HL7
- DICOM
- Data Source Adapters
- CCD/CCDA
- HL7
- Claims
- Survey
- Devices
- Data Sources

Secure Cloud Infrastructure
Empower patients with access and control

- Easy/automated data collection from diverse sources
- User-friendly presentation of consolidated records
- Easy management of access and sharing of personal health record
- Easy communication with researchers and providers

Improving accuracy and security leveraging patient involvement

- Patient-managed identity
- Patient-managed consent/authorization
Link researchers to potential participants

Enable researchers to:

• Push research information to people to enlist participation
• View/manage participation
• Access/automatically receive data after authorization
  • Comprehensive/consolidated digital health records
  • Other health-related data
• Configurable data
Patient-Reported Outcomes — Harnessing Patients’ Voices to Improve Clinical Care
Ethan Basch, M.D.

Symptom management is a cornerstone of clinical care, particularly for patients with chronic conditions. Yet patients’ symptoms and physical impairments go undetected by health care providers as much as half the time, particularly between clinic visits. As a result, we miss opportunities to intervene and alleviate suffering. Moreover, incomplete documentation of this information in the electronic health record (EHR) limits our ability to understand key patient outcomes when we aggregate EHR data for comparative effectiveness research or quality-of-care assessments.

Recent advances in technology and survey methods provide a potential solution in the form of patient-reported outcomes (PROs) recorded electronically — using simple but methodologically robust questionnaires, completed by patients at or between visits over the Internet or on a smart device, with data transmitted into the EHR. Clinicians can receive automated notifications about worrisome symptoms or functional issues, such as severe dyspnea or reduced physical activity in an outpatient with heart failure. They can review longitudinal PRO reports at visits and import that information into their EHR notes as a part of the review of systems. There is evidence that this approach can improve patients’ quality of life, enhance patient–clinician communication, reduce emergency de-

Ideally, PRO collection would be enabled for patients on their own smart devices in flexible user-configurable formats, perhaps through text messages, automated telephone systems, or downloadable apps.
Facilitating Communication

Engage.

A new way to communicate.

A method for delivering customized surveys directly to users’ mobile devices.
Is Digital Health Finally About to Turn All That Hype Into Results?

by Sy Mukherjee  @the_sy_guy  MAY 4, 2016, 5:55 PM EDT
People as stewards of their own data, empowered by tools that enable them to acquire, harmonize and share...so that they may become active partners in pursuit of better health for themselves – and for those that follow them.
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- Maintain a comprehensive/consolidated health record that’s easy to understand
- Take control of their own health record for different purposes
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Questions

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• Please complete online session evaluation