Welcome to the Duke CTSI Virtual Town Hall

July 21, 2017

Hosted by Ebony Boulware, MD, MPH

Director, Duke Clinical & Translational Science Institute
Chief of the Division of General Internal Medicine within the Department of Medicine
Vice Dean for Translational Science
Associate Vice Chancellor for Translational Research in the School of Medicine

This presentation is being recorded.
A Few Housekeeping Notes

• Q&A time will follow presentation.

• During the presentation, use the chat box in WebEx to ask questions.

• You have been muted upon entry to this WebEx. Click the microphone by your name in the participant list to unmute.

• Please remain muted until you need to speak. This minimizes background noise.

• When you speak, identify yourself by name and work area.

• This WebEx is being recorded and will be posted on the CTSI website.
Human Adaptation to a Sea-change in Information Science: A Challenge for the Next Decade

Robert Califf, MD, MACC
Vice Chancellor for Health Data Science
Director, Center for Integrated Health Data Science
Donald F. Fortin, MD Professor of Cardiology
Personal Perspective

• I have witnessed a revolution in healthcare
• During my professional career
  • Insights into public health measures like blood pressure and fundamentals of diet have advanced dramatically
  • Amazing drugs and devices have been developed and deployed
  • We have taken on the menace of tobacco and we’re winning the battle
  • Age specific mortality has been reduced by over 50% with resulting increases in American and global longevity and functional status
The Next Revolution

• **Will result from the transformation of information**

• In order to apply this fundamental revolution to improve health and quality of life, we must:
  • Learn how to share and create business models that work to improve sharing
  • Invest heavily in curating information
  • Work together to develop social and ethical constructs to deal with privacy, confidentiality and security
  • Create a workforce that can both create new methods and integrate information into practice
  • Give the workforce time to invest in knowledge generation as a routine part of practice
  • Work with the public to gain support and understanding
“Chronic, multifactorial disease problems can be studied, but not by the methods of the present or past. If one wishes to create useful information... computer technology must be exploited.”
—Eugene Stead, MD

1960s

• Dr. Eugene Stead developed concept of “computerized textbook of medicine”
• Formation of the Duke Databank for Cardiovascular Diseases
<table>
<thead>
<tr>
<th>Route</th>
<th>Name of Patient</th>
<th>Age</th>
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Mortality experiences of the 8 Americas

Mortality in the 20th Century

- Better treatment of cardiovascular disease, low birth-weight infants
- Reduced infectious disease mortality (clean water, sewers, antibiotics, better nutrition)
All-cause mortality, ages 45–54 for US White non-Hispanics (USW), US Hispanics (USH), and six comparison countries: France (FRA), Germany (GER), the United Kingdom (UK), Canada (CAN), Australia (AUS), and Sweden (SWE).
Life Expectancy at Birth by County, 2014

Counties in South Dakota and North Dakota had the lowest life expectancy, and counties along the lower half of the Mississippi, in eastern Kentucky, and southwestern West Virginia also had very low life expectancy compared with the rest of the country. Counties in central Colorado had the highest life expectancies.
Change in Life Expectancy at Birth by County, 1980 to 2014

Compared with the national average, counties in central Colorado, Alaska, and along both coasts experienced larger increases in life expectancy between 1980 and 2014, while some southern counties in states stretching from Oklahoma to West Virginia saw little, if any, improvement over this same period.
Geographic Health Information Systems: A Platform To Support The ‘Triple Aim’

Abstract
Despite the rapid growth of electronic health data, most data systems do not connect individual patient records to data sets from outside the health care delivery system. These isolated data systems cannot support efforts to recognize or address how the physical and environmental context of each patient influences health choices and health outcomes. In this article we describe how a geographic health information system in Durham, North Carolina, links health system and social and environmental data via shared geography to provide a multidimensional understanding of individual and community health status and vulnerabilities. Geographic health information systems can be useful in supporting the Institute for Healthcare Improvement’s Triple Aim initiative to improve the experience of care, improve the health of populations, and reduce per capita costs of health care. A geographic health information system can also provide a comprehensive information base for community health assessment and intervention for accountable care that includes the entire population of a geographic area.

Donald Berwick and colleagues’ influential 2008 Health Affairs article, “The Triple Aim: Care, Health, and Cost,” describes a conceptual framework developed by the Institute for Healthcare Improvement for improving the US health care system.4 In the Triple Aim, the institute has identified three aims that must be simultaneously pursued: improve the experience of care, improve the health of populations, and reduce per capita costs of health care. In this article we introduce and describe information technology designed to support health systems and communities in achieving the Triple Aim. We demonstrate how this technology can be used to assess the health of neighborhoods and exposures; health services application is better manage patient flow to emergency departments (EDs), and a clinical population health application designed to care for people with diabetes at the individual, neighborhood, and county levels.

The ‘Triple Aim’ has been used by a number of health systems as a conceptual framework for designing health system improvement programs.2 The abundant electronic health data that are accumulating are highly relevant to managing population health and developing new insights.3 Until recently, however, these data have been dispersed across many locations, with little integration.4 As integrated health systems are becoming more widespread, these data are being...
Patients with diabetes use ED more
Diabetes risk algorithm model 4

This model predicts the likelihood that a patient with diabetes will have a serious medical outcome. It is based on the patient's medical and social data in 2011, plus 2016 neighborhood features. This includes the number of grocery stores, fast food restaurants, religious institutions, and medical clinics in the area where the patient resides. It also includes a count of crimes that were committed in the neighborhood, and the distance to the nearest park.
Spatially-enabled data architecture and analytics (who, what, where)

Decision support systems

Accountability: real-time monitoring and evaluation (e.g., weight, HbA1c, vision, CVD, cancer, nutrition, nephropathy, neuropathy, physical activity, self-care/management, health system trust)
Our National Clinical Research System is Well-intentioned But Flawed

- High percentage of decisions not supported by evidence*
- Health outcomes and disparities are not improving
- Current system is great except:
  - Too slow, too expensive, and not reliable
  - Doesn’t answer questions that matter most to patients
  - Unattractive to clinicians & administrators

We are not generating the evidence we need to support the healthcare decisions that patients and their doctors have to make every day.

*Tricoci P et al. JAMA 2009;301:831-41
Which treatment is best for whom?
High-quality evidence is scarce.

<15% of guideline recommendations supported by high-quality evidence
Trial hyperinflation

Figure 3. Mean Total Grant Cost per Patient Index, Biomedical R&D Price Index, and pooled hedonic indexes, 1989–2011

- Mean Total Grant Cost per Patient Index
- Biomedical R&D Price Index

Pooled hedonic index with trial phase, therapeutic area, and year as indicator variables

Source: Authors' calculations based on Medidata Solutions, Inc.'s, PICAS® database.
PCORnet®: the National Patient-Centered Clinical Research Network

An innovative initiative funded by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet is a large, highly representative, national patient-centered clinical research network.

Our vision is to support a learning U.S. healthcare system and to enable large-scale clinical research conducted with enhanced quality and efficiency.

Our mission is to enable people to make informed healthcare decisions by efficiently conducting clinical research relevant to their needs.
With PCORnet®, we have developed a nationwide functional research network that...

- **Engages** people, clinicians, and health system leaders throughout

- **Creates** infrastructure, tools, and policies to support rapid, efficient clinical research

- **Utilizes** multiple data sources including electronic health records, insurance claims data, data reported directly by people, and other data sources
Patients, caregivers and others interested in clinical research provide a unique voice

- **Patients and Caregivers** help identify knowledge gaps by sharing their experiences with the daily burden of disease conditions, their thoughts on opportunities for treatment.

- **Patient and stakeholder engagement**, both within the Partner Networks and at the broader PCORnet level, is embodied within the **PCORnet Governance Policy**.

- **Patients are represented** on each of the **PCORnet Committees**.
PCORnet® embodies a "network of networks" that harnesses the power of partnerships.
PPRNs

American BRCA Outcomes and Utilization of Testing Patient-Powered Research Network (ABOUT Network)
University of South Florida

ARthritis patient Partnership with comparative Effectiveness Researchers (AR-PoWER PPRN)
Global Healthy Living Foundation

CCFA Partners Patient Powered Research Network
Crohn's and Colitis Foundation of America

Collaborative Patient-Centered Rare Epilepsy Network (REN)
Epilepsy Foundation

Community and Patient-Partnered Centers of Excellence for Behavioral Health
University of California Los Angeles

Community-Engaged Network for All (CENA)
Genetic Alliance, Inc.

COPD Patient Powered Research Network
COPD Foundation

DuchenneConnect Registry Network
Parent Project Muscular Dystrophy

Health eHeart Alliance
University of California, San Francisco (UCSF)

ImproveCareNow: A Learning Health System for Children with Crohn's Disease and Ulcerative Colitis
Cincinnati Children's Hospital Medical Center

Interactive Autism Network
Kennedy Krieger Institute

Mood Patient-Powered Research Network
Massachusetts General Hospital

Multiple Sclerosis Patient-Powered Research Network
Accelerated Cure Project for Multiple Sclerosis

National Alzheimer's and Dementia Patient and Caregiver-Powered Research Network
Mayo Clinic

NephCure Kidney International
Arbor Research Collaborative for Health

Patients, Advocates and Rheumatology Teams Network for Research and Service (PARTNERS) Consortium
Duke University

Phelan-McDermid Syndrome Data Network
Phelan-McDermid Syndrome Foundation

PI Patient Research Connection: PI-CONNECT
Immune Deficiency Foundation

Population Research in Identity and Disparities for Equality Patient-Powered Research Network (PRIDEnet)
University of California San Francisco

Vasculitis Patient Powered Research Network
University of Pennsylvania
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<th>CDRNs</th>
<th>ADVANCE</th>
<th>Accelerating Data Value Across a National Community Health Center Network (ADVANCE)</th>
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<td>National PEDSnet: A Pediatric Learning Health System</td>
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<td>PaTH: Towards a Learning Health System</td>
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<td>Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)</td>
<td>Harvard University</td>
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Resulting in a national evidence system with unparalleled research readiness

For clinical trials

For observational studies

PCORnet represents: ~122 million patients

who have had a medical encounter in the past 5 years

*some individuals may have visited more than one Network Partner and would be counted more than once
Sets of Facts per Decision

1000

100

10

5

Human Cognitive Capacity

1990 2000 2010 2020

Proteomics and other effector molecules

Functional Genetics: Gene expression profiles

Structural Genetics: e.g. SNPs, haplotypes

Decisions by Clinical Phenotype

Many tools to dissect individualized health

Health records

Genomics

Poverty

Metabolomics

Food deserts

Proteomics

Patient-specific iPSC-derived cells

Images

mHealth
The challenge: integrating multiple datasets for discovery and implementation
WE’VE MAPPED THE WORLD. 
NOW LET’S MAP HUMAN HEALTH.

Join us on a journey to better understand health and prevent disease.
Google’s mission is to organize the world’s information and make it universally accessible and useful.
Baseline Study

10,000 participants
All-comers: healthy → disease(s)
Proteomics
- Genomics
- Epigenomics
- Transcriptomics
- Metabolomics
- Proteomics

Immune Status

EMR History
Family Tree
Surveys

Oomics
- Coronary Calcium
- Echo
- Electrocardiogram
- OCT
- Chest X-Ray
- Stress Echo
- Study Watch
- Sleep Sensor
- Study Hub
- Clinical labs
- Clinical assessments

( Yearly Onsite Visits )

Screen
Baseline Visit
Year 1 Visit
Year 2 Visit
Year 3 Visit
Year 4 Visit

( Quarterly Onsite, Online, Phone )

Duke Clinical & Translational Science Institute
Scalable & standardized tools

~6TB
Data per visit

SAMPLES
- SERUM
- WHOLE BLOOD
- PBMCS
- PLASMA
- STOOL
- SALIVA
- URINE

ASSAYS
- CLINICAL LABS
- GENOMICS (WGS, DNA arrays)
- EPIGENOMICS (Methyl arrays)
- TRANSCRIPTOMICS (RNA-seq)
- IMMUNOPHENOTYPING (CyTOF)
- MICROBIOME (16S rRNA)
- PROTEOMICS
- METABOLICOMICS

Consent Widget
Survey Widget
Administrator Portal
Mobile App
Sensors
Molecular Platforms
Data Analytics
Etc.

External/at clinic site
In-house, each now applied in multiple sclerosis study
External, internalization planned

Duke Clinical & Translational Science Institute
Smartphone

Cardiac and Activity Monitor

Sleep Sensor
We want to create an experience people can get excited about.
We want to create an experience people can get excited about.
Aggregated & searchable participant data
Precision medicine for the population, and the patient.

“It is more important to know what sort of person has a disease than to know what sort of disease a person has.”

*Hippocrates*
### Cures provisions (Sec. 3022)

- Requires FDA to establish a program to evaluate the potential use of real world evidence to:
  - Help support the approval of new indications for an approved drug
  - Help support or satisfy post approval study requirements

### PDUFA RWE provisions

- Tracks with Cures Act
- Requires FDA to establish a program to evaluate the potential use of real world evidence to:
  - Help support the approval of new indications for an approved drug
  - Help support or satisfy post approval study requirements

### Reinforcing of a Learning Health Care System:

- Doesn’t change approval standards, rather it better supports and enables use of data and evidence on outcomes that are hard to get from traditional RCTs (e.g., outcomes that are too costly, too small populations with particular clinical features, too long follow-up needed, diff impact in diff clinical settings, etc.)
- Learning from real-world patient experiences can support better informed health care decision-making by a range of stakeholders
Real World Data and Efficacy

Real-world evidence can be used across a wide spectrum of research, ranging from observational studies to studies that incorporate planned interventions, whether with or without randomization at the point of care.

Incorrect to contrast the term “real-world evidence” with the use of randomization in a manner that implies that they are disparate or even incompatible concepts.

Must consider the components of such trials that are critical to obtaining valid results and minimizing bias.
For Big-Data Scientists, ‘Janitor Work’ Is Key Hurdle to Insights

By STEVE LOHR  AUG. 17, 2014
The New Einsteins Will Be Scientists Who Share

From cancer to cosmology, researchers could race ahead by working together—online and in the open

By MICHAEL NIELEN

In January 2009, a mathematician at Cambridge University named Tim Gowers decided to use his blog to run an unusual social experiment. He picked out a difficult mathematical problem and tried to solve it completely in the open, using his blog to post ideas and partial progress. He issued an open invitation for others to contribute their own ideas, hoping that many minds would be more powerful than one. He dubbed the experiment the Polymath Project.

Several hours after Mr. Gowers opened up his blog for discussion, a Canadian-Hungarian mathematician posted a comment. Fifteen minutes later, an Arizona high-school math teacher chimed in. Three minutes after that, the UCLA mathematician Terence Tao commented. The discussion ignited, and in just six weeks, the mathematical problem had been solved.
Center for Integrated Health Data Science*
Catalyzing discovery and transforming care

*name to be finalized
Shaping future of health care: streamlining knowledge generation, research, innovation and translation

Micro learning environments into hospitals & health delivery systems
Make healthcare more efficient, accessible and personalized

LHS Duke Heart, DCI, Primary Care and Mental Health..etc.,
Tools and methods to extract real value

Translational Health

Business Incubation & Entrepreneurship

Data Sciences

Big Data & Medical IoT

Organized medicine driven by data and growth of digital consumerism

Programs to accelerate and translate research and innovations to address healthcare needs of populations

Venture & market bridge for translations into business to develop the new healthcare ecosystem

National System of Evidence Generation

Duke Clinical & Translational Science Institute
Duke Center for Integrated Health Data Science to shape healthcare of the future

A cross-campus initiative to advance health research, translation and innovation

Mission:
Transforming health through targeted discovery science and implementing effective translational science and clinical care

**approach**
Catalyze quantitative science research initiatives to address high-impact challenges in health, healthcare and discovery

**strategy**
Deploy Duke’s trans-disciplinary excellence in clinical care delivery, clinical knowledge quantitative sciences and data infrastructure to create cutting-edge knowledge and sustainable results

**goal**
Engage Duke Health clinicians, bio-science and campus-wide scholars in data science to create knowledge through research and innovation, and translate to improve delivery of care at Duke and at a national level. Invent the future of healthcare.
Strengthening discovery ecosystem

Deliberate analytical inter-disciplinary collaborations (basic-clinical-computational and data science) to

• Develop the data and application building blocks to advance and support 21st century basic science research and discovery in health

• Support early-stage research to accelerate breakthroughs in drug discovery, diagnostics and development of transformative treatments

• Create genomics and molecular applications to advance precision & personalized medicine

• Advance discovery and applications in public and population health
Duke Center for Integrated Health Data Science to shape healthcare of the future

- Effective data science strategy to organize data and to create knowledge and tools to improve the safety, quality, and efficiency of care
- Shape and lead the platform for 21st century cures initiatives
- System for Evidence Generation
- Micro learning environments for learning health systems
- Platform for transformation of healthcare delivery model
- Market translation through incubation and entrepreneurship
Duke Center for Integrated Health Data Science

- **Data-Driven Team science**
  - Clinically important “Grand Challenges” at intersection of health, healthcare and data science
  - Interdisciplinary research teams: data scientists, clinicians, students and implementation science experts
  - Approximately five projects per year, each for 12 months or more

- **Support structure**
  - Robust computing and data infrastructure
  - Implementation support and living-lab infrastructure
  - Data curators
  - Project management

- **Academic and community engagement**
  - Methodological Faculty Fellows, provide leadership and visibility
  - PhD Graduate Scholars, jointly advised by clinician and faculty data scientist
  - Educational programs and workforce development
  - Translation into populations – local and national.
Integrated Health Data Science

Strategic Domains
- CRU/CSU 1*
- CRU/CSU 2*
- CRU/CSU 3*
- CRU/CSU N*

Functional Cores
- Quantitative and Data Science Scholars and Data Curators
- Implementation Science and Translational Clinics
- Project management and program management
- Robust Data and Computing Infrastructure

*Population Health, Precision Medicine, Patient Engagement, Clinical Effectiveness, Business and Policy effectiveness are representative themes
Stakeholder engagement through Duke Center for Integrated Health Data Science

Integrated health data science

SoM Depts, Centers & Institutes

Leveraging all of Duke: Clinically driven Challenges

Leveraging all of Duke: Quantitative Science

B&B, Pop Health, Stats, Pratt/CS

Computing infrastructure DHTS & OIT

Education and Methods
iiD, Duke Stats, B&B, Pop Health

Implementation and Translation at Duke Health and local community

National Translation through Learning Health System and evidence generation networks

DIHI – DUHS - PDC

Duke Clinical & Translational Science Institute
Center for Integrated Health Data Science

Proposed Structure

Board Chair: Rob Califf (internal vision & outward projection)
Board: L Carin, W Fulkerson, M Klotman, S Kornbluth, E Peterson, Jeff Ferranti and E Washington

Faculty co-directors:
TBN (clinical) and E. Huang (data science)
Deputy director: Amy Herring (Stats)

Structural considerations:
• Configured as a cross-campus entity with dual reporting
• School Of Medicine: primary administrative home for the entity
• Administrative functions and resources in existing centers and institutes will be leveraged
• Educational programs in Campus and School of Medicine will be used to develop next generation of workforce
• Some core administrative and business development capabilities will be developed within the entity
Center focus areas

The center will focus on healthcare and associated data in all its forms:

**Discovery science:** Data from the most challenging and important areas of basic health sciences; accelerate discovery by use of new platforms for basic science research

**Clinical:** integrating data from health records claims and other sources (genetic data, and omics, etc.); drive clinically-motivated research challenges

**Business process and model:** transform delivery using technology, data and business model innovation; links to policy and regulations;

Potential kickoff projects

1. Neuroscience area
2. Discovery Science area
3. MSSP, Duke Connected Care claims analysis (Eugenie Komives)
4. Surgery - predicting risk & complications (A Kirk)
5. Automated event adjudication through machine learning (DCRI)
6. Duke Heart – Project eCAD (M Patel/A Hernandez)
7. SEDI analysis (B Granger)
Center Milestones and Goals

- Initial funding to be provided by Duke and Duke Health to constitute Center, with objective of external awards to manifest sustainability

- The center should help others create generalizable knowledge and scholarly publications

- Milestones
  - Win awards to help support training of the faculty, as well as graduate/undergraduate students
  - Changing health and technology
  - Secure awards to advance science, implementation and scaling

- Goal: Within 5 years, have much of the Center training supported by grants (large training grants); team science and PhD theses result in grants, enhancements in Duke Health, and/or startups
Amplification of Strategic Investments

- **Provost’s Investment**
  - To advance Data Science and associated moonshot projects

- **Chancellor and Provost’s Initiative**
  - To accelerate health apps

- **Health Enterprise Investment**
  - The next-generation data warehouse for health research and translation

- **I & E (Translation, entrepreneurship and commercial partnerships)**

- **CTSA (Informatics and Analytics Work Space for translational research)**

- **Population Health**
  - Qualified entity status for Medicare/Medicaid to advance population health initiatives

- **iID (Interdisciplinary program to increase "big data" computational research)**

- **Center for Applied Quantitative Sciences in Health**
“Google told me I have cancer”
Editor’s Note:
Don’t Google for any of the above!!!
Health Search Categories

Conditions + Treatments + Symptoms are the key concern

DINs

- Condition 51%
- Treatments 13%
- Home Remedies 13%
- Symptoms 9%
- Wellness 6%
- News 4%
- Shopping 3%
- Fitness 3%
- Reproduction 3%
- Other 3%

Conditions + Treatments + Symptoms are the key concern.
2016: Closed the loop on health searches!

Symptom Search
US, BR

Condition KPs
US, BR, IN + 20 countries

Drugs KPs
US

Health Search products
Data Activation and Testing Outcomes

What Impacts Behavior?

A
CONTROL

B
VARIATION

Verify
Digital Transformation

2010
- Individual Productivity
- IT Silos
- Data on premise, hard to access, analyze and use
- Productivity tools built for individual, local usage
- IT focusing on where it computes

2020
- Collective Intelligence
- Distributed Computing
- Data stored in cloud, simple to query
- Collaborative, cloud based productivity applications
- Machine learning drives deep, actionable insights
- IT changing how it computes
Questions?

Don’t forget to unmute yourself!
Thank you for joining!

A recording of this presentation will be posted on www.ctsi.duke.edu

Sign up to receive newsletters and notification of the next CTSI Quarterly Virtual Town Hall at https://www.ctsi.duke.edu/news/newsletters

The next Town Hall will be Friday, October 6: Trial Innovation Network (TIN)