Health Affairs Briefing

Using Big Data To Transform Care

Alan Weil
Editor in Chief
National Press Club
July 9, 2014
Health Affairs
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Creating Value Through Big Data: An Overview

Joachim Roski, PhD MPH
Booz Allen Hamilton
Data Availability Is Exploding

- In 2012 healthcare data worldwide amounted to approximately 500 petabytes (one petabyte equals $10^{15}$ bytes of digital information), by 2020 this amount will likely increase to 25,000 petabytes; an increase by 50 times.
The 3 “Vs” Of Big Data

• **Volume.**
  – Massive amounts of data strain the capacity and capability of traditional data storage, management, and retrieval systems such as data warehouses.
  – Big data requires flexible and easily expandable data management solutions.

• **Variety.**
  – Big-data approaches enable the efficient linking and analyses of disparately formatted data to answer particular operational, business, or research questions.

• **Velocity.**
  – Most traditional health IT infrastructures are not able to process and analyze massive amounts of constantly refreshed, differently formatted data in real time. Big-data infrastructure makes it possible to manage data more flexibly and quickly than has been the case.

Value

$300 billion/yr.
Enabling IT Infrastructure

• Data Lakes instead of data warehouses
  – Multiple data formats
• No need to transform raw data
• Meta-tagging of data with critical info
• Emergence of Cloud Service Providers
  – Data Security & Privacy
  – Flexible storage & computing capacity
Data Still Needs To Be Interpreted

- Data science combines expertise in
  - Domain/Health
  - Mathematics/Analytics
  - Computer Science

- Data Science supports shifting between deductive (hypothesis-based) and inductive (pattern-based) reasoning.

- May facilitate discovery across different scientific disciplines & explanatory models
ADVANCED ANALYTICS
Deals with smaller datasets but uses advanced techniques to analyze the impact of future scenarios.

BASIC ANALYTICS
Relies on historical observations to help avoid past mistakes and duplicate past success.

BIG DATA ANALYTICS
Can fuse different data types on a massive scale resulting in predictive and real-time analysis capabilities.

BIG DATA COMPUTING
From a systems perspective, data becomes more consolidated while analytic workflows are more streamlined and automated.

Analytic Complexity

Small amounts of data or samples (megabytes to gigabytes)

Large (or all) Amounts of data (gigabytes to petabytes)

Size of Data
Critical Policies & Outlook

• Policies for review
  – Data security
  – Privacy
  – Consent
  – Data sharing
  – Stewardship

• Where are we going?
  – Experimentation – not wide scale change yet
  – Perceived “greater” lack of control over data security with Big Data
  – Organizational cultures are challenged
  – Data analysis in the hand of the end-user
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Panel 1: Using Big Data At The Point Of Care
Deriving Value From Analytics In Healthcare: Six Key Use Cases

Suchi Saria, PhD
Johns Hopkins University

David Bates, MD MSc
Lucila Ohno-Machado, MD PhD
Anand Shah, MD MSc
Gabriel Escobar, MD

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Adoption: Big Data in Healthcare

• Many multibillion dollar industries (search, retail, entertainment) where predictive analytics are driving business

• Uptake in healthcare has been limited.
  – Data more easily accessible
  – Incentives like accountable care and bundling
  – Increasing buy-in for big data technologies
1. Triage: ex 1

- KPNC pilot: screening newborns for early onset sepsis
  - Analytic program assesses maternal risk factors to assign preliminary risk
  - Combined with clinical findings at birth to predict overall risk
  - Based on guideline, sepsis workup is provided.
  - Result in 240,000 fewer US newborns/year treated with antibiotics.

Escobar et al., Pediatrics 2014
1. Triage: ex 2

- ‘Electronic Apgar’
  - Using routinely collected bedside monitoring data
  - Identify within first few hours of birth, infants at risk for major complications downstream.
  - Implications for staffing, transport, and management

Saria et al., Science Trans. Med. 2010
2. Hospital Readmissions

3. Highest Cost Users
   • 5% account for 50% of resource use
   • Predict high cost users and developed targeted interventions

4. Adverse Events
   • Monitoring risk of AEs (e.g., renal failure, infection) and Adverse Drug Events (ADEs)
5. **Decompensations**
   - Identify sudden worsening of patient state.
   - Requires continuously observing multiple information streams.

6. **Diseases Affecting Multiple Organ Systems**
   - Costliest conditions to manage (e.g., rheumatoid arthritis, inflammatory bowel disease)
   - Predict trajectory for each patient
Policy implications: Research

• **Federal support** to move from potential to realization
  – More systematic evaluations
  – Methods for increasing prediction relevance
    • Tailor predictions (e.g., behavioral versus socioeconomic factors for the individual); fuse novel data sources (e.g., social, mobile)
    • Make recommendations actionable
    • Reduce false positives when cost of interventions is high (e.g., case management)
Policy implications: Payment

• Current provisions of the ACA may not be sufficient to get providers incentivized to reduce cost

Policy implications: Privacy

• Many thorny issues (e.g., linking of many data sources)
• HIPAA does not address many relevant issues as more data sources get linked.
Policy implications: Regulation

• Should these data products be regulated?
  – Regulatory oversight and innovation
  – The FDA SIA working group released draft report recommending that FDA premarket evaluation of health IT apps and analytics would not be beneficial.
Key Use Cases in the Near Term

• Eventually, value derived from integrating clinical, claims, outcome, genomic, behavioral data.

• In near term, tremendous promise in six key use cases using predictive analytics.
Optum Labs

Building A Novel Node In The Learning Health Care System

Paul J. Wallace, MD
Chief Medical Officer, Optum Labs

Nilay Shah, PhD, Mayo Clinic
Taylor Dennen PhD, Paul Bleicher MD PhD, and William Crown PhD, Optum Labs

Health Affairs
Rapid Change Begets New Opportunities

• Rapidly growing amounts of data, new information resources and expanding care delivery approaches are driving unprecedented change in US health care

• Optum Labs is a novel collaboration bringing together diverse industry participants to foster discovery, promote innovation and implement findings into health care practice
Optum Labs: Diverse Partners, Rich Data

- Founders: Optum and Mayo Clinic
- 11 initial collaborators include delivery systems, academics, patient/consumer advocates, drug and device manufacturers, and provider alliances
- Designed to bring together and link extensive and complementary data sets
- Providing secure, linked, HIPAA de-identified research ready administrative and EMR data on over 100 million US lives
An Integrated Approach

- A sustainable, learning health care system with prototyping and feedback connecting practice and research
  - Practitioners are engaged in research conceptualization and prioritization
  - Secure research enclaves safeguard and enable investigator access to rich and diverse data
  - Advanced data exploration and visualization tools accelerate discovery
New Insights: Methods And Findings

• Evolving methods for aligning findings from observational data with clinical trials

• Focus on: patient and practitioner behavior and health outcomes; disparities and variations in care; heterogeneity of treatment response

• Initial new and extended findings on diabetes care, knee replacement, and hepatitis C
Emerging Insights

• Complementarity of various data sources
• The patient as an “N of 1”
• Learning about learning
  – Organizational and administrative successes and challenges,
  – Implications for policymakers, including organizational governance and sustainability
PEDSnet: How A Prototype Pediatric Learning Health System Is Being Expanded Into A National Network

Christopher B. Forrest, MD, PhD
Children’s Hospital of Philadelphia
University of Pennsylvania

The work is supported by Agency for Healthcare Research and Quality Grant No. R01 HS020024, National Institutes of Health Transformative Research Grant No. R01 DK085719, ImproveCareNow Care Centers, and Patient-Centered Outcomes Research Institute Grant No. CDRN-1306-01556.
Learning Health System

• Communities of patients, clinicians, and healthcare organization leaders

• Create big data resources useful for...
  – Knowledge generation (research) &
  – Knowledge application (quality).
Remission Rates For Children And Youth With Inflammatory Bowel Disease

**Source** Data are from the ImproveCareNow pediatric inflammatory bowel disease registry for 2007-14. **Notes** Each blue dot represents the percentage of patients in remission among care centers with more than 75 percent of their patients enrolled in Improve CareNow in a given month. The figure shows the upper and lower confidence limits (dashed red lines in red) and the mean (green solid lines).
PEDSnet Conceptual Model

Pediatric big data → knowledge generation → knowledge application → learning cycle → Improved patient & system outcomes
PEDSnet Vanguard Institutions

2.5% of the Nation’s Children
PEDSnet Partners

Disease-specific Networks

– ImproveCareNow
– National Pediatric Cardiology Quality Improvement Collaborative
– National Healthy Weight Network

Data Partners

– IMS Health
– Express Scripts
Key Message

Creating big data within the context of purposefully designed learning health systems that produce new knowledge (via research) and apply that knowledge at the point of care (via quality improvement) will be necessary to substantively improve the health and lives of patients.
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Panel 2:

Research Issues

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Patient-Powered Research Networks Aim To Improve Patient Care And Health Research

Rachael L. Fleurence, PhD
Program Director CER Methods and Infrastructure
Patient-Centered Outcomes Research Institute (PCORI)
PCORnet Launched Q1 2014

- Goal is to improve the **speed, efficiency** and **cost-effectiveness** of **clinical research** in the United-States by **engaging patients** and leveraging **electronic health data**

- **Better evidence** will lead to **improved patient health outcomes**
Patients Powering Research Networks

• 18 patient powered research networks funded alongside 11 clinical research networks

• Patients are engaging by:
  – Contributing data securely, setting privacy policies;
  – Increasing network membership;
  – Prioritizing research and disseminating future results;
  – Participating in leadership and governance.
Challenges Highlights

• Successfully collecting and harmonizing data from multiple sources
• Increasing patients’ willingness to participate in research
• Establishing patient trust with respect to the use of data
• Meaningfully engaging patients in governance and leadership
The PCORnet Opportunity: Making A Real Difference For Patients And Their Families

Until now, we have been unable to answer many of the most important questions affecting health and healthcare

By combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patients’ priorities and speed the creation of new knowledge to guide treatment on a national scale.
Bed Occupancy And Mortality

Flemming Madsen
Allergy & Lung Clinic Elsinore

Madsen Linneberg Ladelund

HealthAffairs
Background

• A root cause analyses indicated that chronic bed shortage created hyperefficient hospitals with reduced patient safety

• Bed shortage (reduced staff to patient ratio)
  – might reduce patient safety by increasing omissions, slips, lapses and errors
  – increases productivity if combined with a high patient turnover
Background
Methods

• Creating the “Bed occupancy research database”

• Seventeen million hospital admittances from 1995 to 2012 was compiled and bed occupancy was calculated for all Danish hospital departments with a temporal resolution of 15 min (664,661,376 records).

• 2.65 million admittances to departments of internal medicine were selected for statistical analyses of mortality
Results And Conclusion

• A strong association between bed occupancy and mortality was found
  – 9% increase in mortality when bed occupancy was high
  – 1% increase in mortality per 10% percent increase in bed occupancy from 80%

• A strong association between admittance outside normal work hours and mortality was found
  – A confirmatory result
Perspective

• **Focus on the health effects of high bed occupancy should be increased**

• **Root course of excessive bed occupancy should be determined**
  
  – Planned?
  – Lack of ressources?
## Implementing Electronic Health Care Predictive Analytics: Considerations And Challenges

<table>
<thead>
<tr>
<th><strong>Bin Xie, PhD</strong></th>
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<tr>
<td>Health Services Research Manager, PCCI</td>
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<td>Dallas, TX</td>
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Authors: Ruben Amarasingham, Rachel E. Patzer, Marco Huesch, Nam Q. Nguyen, Bin Xie

Funding: Gordon and Betty Moore Foundation

*Health Affairs*
Electronic Health Care Predictive Analytics And PCCI

- We define electronic health care predictive analytics (e-HPA) as the technologies or software systems that can autonomously employ—and sometimes reengineer, modify, or update—clinic risk prediction models.

- Parkland Center for Clinical Innovation (PCCI) is a non-profit research and development corporation Dallas, Texas that specializes in real-time predictive and surveillance analytics for healthcare.

Challenges And Recommended Actions

**EXHIBIT 1**

### Key Challenges And Recommended Actions To Integrate, Test, And Disseminate Electronic Health Care Predictive Analytics (E-HPA)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Recommended action</th>
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<tbody>
<tr>
<td><strong>TESTING THE MODEL IN A REAL-WORLD SETTING UNDER APPROPRIATE SUPERVISION</strong></td>
<td>Establish a health care system operations team to oversee implementation</td>
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<tr>
<td>Appropriate approval and oversight of implementation</td>
<td>Work with key stakeholders to develop and implement relevant clinical protocols</td>
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<td>Stakeholder engagement</td>
<td>Ensure that the health care system operations team assesses the need for human subjects protection</td>
</tr>
<tr>
<td>Human subjects research protection</td>
<td>and IRB approval</td>
</tr>
<tr>
<td>Protection of patients’ privacy</td>
<td>IRB determine the need for patient consent, if applicable</td>
</tr>
<tr>
<td>Data assurance</td>
<td>Conduct pilot implementation of e-HPA</td>
</tr>
<tr>
<td><strong>BROAD IMPLEMENTATION OF THE MODEL IN A HEALTH CARE SETTING</strong></td>
<td>Apply lessons learned from above</td>
</tr>
<tr>
<td>Patient privacy protection, patient consent, approval and oversight, stakeholder engagement</td>
<td>Follow standards to ensure interoperability within and across health systems</td>
</tr>
<tr>
<td>Interoperability of health systems</td>
<td>Ensure open sharing of HPA methods to foster collaboration across health systems</td>
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<tr>
<td>Transparency of HPA within health systems</td>
<td></td>
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<tr>
<td><strong>LONG-TERM CHALLENGES</strong></td>
<td>Ensure that shared patient-provider decision making is not replaced by e-HPA</td>
</tr>
<tr>
<td>Impact on doctor-patient relationships</td>
<td>Implement medical school education and clinical workforce training in e-HPA</td>
</tr>
<tr>
<td>Medical education and training</td>
<td>Align patient care quality and population health management goals; have stakeholders (including</td>
</tr>
<tr>
<td>Sustainability of e-HPA in health care systems</td>
<td>paying, vendors, and health systems) advocate for reimbursement incentives for HPA in care processes</td>
</tr>
</tbody>
</table>
Conclusions

• E-HPA has huge potential;

• It matters a great deal how we implement e-HPA in a single institution and how we scale up across the country;

• PCCI has first hand experiences in some of the challenges in such implementations, and we will be more than thrilled to hear from you

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Panel 3:
The Role Of The Federal Government
A Rapid Learning Health System

• Proposed in *Health Affairs* theme issue, 2007
  – A rapid-learning system learns as quickly as possible about the best treatment for each patient – and delivers it...It draws on electronic health records and the power of big data to access large volumes of information from a variety of sources at high speed.
A Rapid Learning Health System

• What happened (2007-2013)?
  – Policy studies & reports
  – Investments: NIH (BD2K. biobanks), FDA (Sentinel, 150M), PCORI (PCORnet, 100 M), CMS ($10B Innovation Center), ASCO (RL cancer system); UK (64M, biobank); global data sharing (41 countries)

• A RL clinical research system with several hundred million patients. “Electrifying” potential (Francis Collins)
RL: A Breakthrough Agenda

• **Challenges For Clinical Research and Development**
  – Implement new clinical research system with several hundred million patient records
  – Modernize clinical trials and registry systems
  – Fund research on national priorities
  – Address Medicare & Medicaid needs (100 M, $10 T spending next 10 years)
  – Analyze genetic factors in disease & treatment
RL: A Breakthrough Agenda

- Improving Comparative Effectiveness Research
  - Actionable evidence for national priorities
  - New technologies – learn as much as possible, as soon as possible
  - International Rx evidence base w/ full (de-identified) data sets
RL: A Breakthrough Agenda

• **Health Information Technology**
  – EHRs + massive genetic data
  – EHRs + Apps

• **Improving Patient Care**
  – Predictive models (physicians & patients)
  – Translating rapid-learning into clinical practice (ASCO’s RL cancer system, PCORI’s national pediatric learning health system, G-8 Alzheimer’s initiative, Project ECHO)
Conclusion

• Investments in a rapid-learning health system now provide a historic opportunity to revolutionize biomedical research, clinical care, and public health.
Leveraging The Big Data Revolution: CMS Is Expanding Capabilities To Spur Health System Transformation

Chris Cox
Acting Director, Office of Information Products and Data Analytics, Centers for Medicare & Medicaid Services
CMS Data Resources

• CMS is the largest single payer for health care services in the US

• 2.5 billion Medicare claims submitted annually
  – Fee-for-service claims (Parts A and B)
  – Part D drug events

• Receive billions of other data points
  – Medicaid claims
  – Assessments
  – Surveys

• Significant additional data sources on the way
  – Medicare Advantage encounter data
  – Quality data
Programmatic Uses of CMS Data: Medicare 30-Day, All Condition Readmit Rate
Open Data: Examples Of Recently Released Data

- Provider Utilization and Payment Data
  - Hospital Inpatient
  - Hospital Outpatient
  - Physician and other Supplier

- Public use files and interactive dashboards at the state, HRR, and county level
  - Chronic conditions
  - Geographic variation
Data-Sharing Programs: Virtual Research Data Center

**ACCESS**
- Researchers use own laptop to securely access data remotely
- Increases efficiency of data sharing and reduces infrastructure costs for data users

**SECURITY**
- No shipping of data on external media
- Users only see data files with the data they need to conduct their project
- CMS can track and monitor use of the data

**PRIVACY**
- Users may only remove aggregated output files; no granular identifiable output may be taken Out of the VRDC
- CMS encrypts all beneficiary identifiers

**DATA & ANALYSIS**
- Users can perform their own analyses and data manipulation in the virtual environment
- Secure File Transfer System allows users to upload their own data and download output files efficiently and securely
Data-Sharing Programs: Other Activity

• CMS is routinely and safely sharing data to support the transformation of the delivery system
  – Qualified Entities
  – Accountable Care Organizations (ACOs)
  – States

• CMS has also allowed beneficiaries full and open access to their Medicare claims data through the Blue Button Initiative
Conclusion

• Breadth and depth of data that CMS collects are significant
• Focusing on data in recognition of the important role that data analytics can play in the transformation of the health care system
• Goals:
  – Internally – continuous performance improvement through data-driven decision making; increase access to consumable analytics across the agency
  – Externally – expand use of CMS data through secure access mechanisms while maintaining privacy
Evolution of Data Resources

• >6 million patients treated annually
  – 151 medical centers
  – ~1000 sites of care
• EHR in use for nearly 3 decades
“1st Generation” analytics

- Performance measures
- Multidimensional cubes
- Dashboards
- Clinical alerts and “reminders”

⇒ Limited access and filtering

⇒ “Alert fatigue” and information overload
“2nd Generation” Analytics

- **Corporate Data Warehouse**
  - 1.5 Petabytes, 80B rows of data
  - 2B outpt encounters
  - 2B prescriptions
  - 2.5B text notes

- **20,000 users**
Current Applications

• Identification of “high-risk” patients
  – ~120 variables from 6 domains
  – High accuracy (C statistic 0.80 to 0.85)
  – Run weekly on ~ 6M primary care pts.

• Evaluation of Patient-Aligned Care Teams
  – Return on investment
  – Effectiveness of implementation
Lessons

• **Importance of data consolidation**
  – “Timeliness vs data integrity”

• **Stronger data governance**
  – Access
  – Training

• **Links to other data sources**

• **Integration of data collection and reporting into routine work flow**
Collaborators

- Joseph Francis
- Carolyn Clancy
- Christopher Nielson
- Karin Nelson
- John Rumsfeld
- Theresa Cullen
- Jack Bates
- Gail L. Graham
For their generous support of the July 2014 thematic issue and this briefing
Panel Four:

Obstacles/Challenges Of Using Big Data

HealthAffairs
Genomic Sequencing: Assessing The Health Care System, Policy, And Big-Data Implications

Julia Trosman


UCSF Center for Translational and Policy Research on Personalized Medicine (TRANSPIERS)

Funded by National Human Genome Research Institute (R01 HG007063)

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Genomic Sequencing:

Unprecedented Promise, Unprecedented Challenges

• Accelerates genomic discovery; has potential to transform clinical care
  – Many genes simultaneously using single test at high speed
  – Drastic cost reduction - “$1000 Genome”
  – Entering care, particularly in oncology

• Policy challenges
  – Integration into health care system
  – Policy development & decision-making
  – Patient and provider challenges

• Big Data challenges
  – Exponential complexity and really “big” data
  – Infrastructure, bioinformatics and analytics, data structures & management
Decisionmakers Need To Understand Sequencing: Our Easy To Use Classification

Sequencing Input
- Which patients are sequenced
- Why patients are sequenced
- What is sequenced

Sequencing Methods
- Technology used
- Extent of sequencing

Sequencing Output
- How findings are examined and reported
- Clinical relevance of findings
Key Policy Issues:

Patient-Centered Care, Reimbursement, Value

Sequencing Could Facilitate Patient-Centered Care

• “Extreme” personalization requires tools and analytics
• Increased data privacy and security concerns

New Coverage and Reimbursement Policies Will Be Needed

• Convergence of care and research challenges coverage framework
• Lack of reimbursement for unvalidated findings, bioinformatics & infrastructure

Economic Value Will Vary

• Value will vary depending on how sequencing is used & perspective
• Requires more complex models than single gene tests
Sequencing: Not When But How

• Our classification provides means to prioritize sequencing applications

• Whether sequencing can achieve potential depends on:
  – How patients and providers value information provided
  – Whether covered by payers & included in guidelines
  – Value: whether benefits to health care system outweighs costs

• UCSF TRANSPERS been addressing policy issues for personalized medicine since 2008
  – Now studies of patient-centered care, reimbursement, & value for sequencing
The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care

I. Glenn Cohen
Professor, Harvard Law School, Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics

Co-Authors:
Ruben Amarasingham, CEO & President PCCI
Anand Shah, VP, PCCI
Bin Xie, Health Services Manager, PCCI
Bernard Lo, President, Greenwall Foundation
One Hypothetical Use Case

• Physician decision on whether to send a patient with moderate organ dysfunction to ICU.

• Evaluation for risk of arrest or adverse event would take hours, limited accuracy.

• The Future: predictive analytics model might ascertain the instantaneous risk for cardiopulmonary arrest of every one of a thousand patients in a given hospital at every second and determine which patients would most benefit from ICU admission.
Phase 1: Acquiring Data

• *Consent and Privacy*: Should we require explicit consent? Is de-identification possible? Should patients be given notice?

• *Equitable Representation*: The importance of community engagement.

Phase 2: Building and Validating Model

• *Patient-Centered Perspectives*: How to ensure patient role in governance? Trust models? Analogy to biobanks.

• *Validation*: How rigorous? Who decides?

• *Transparency*: Key variables and relative contribution disclosed? Will doctors trust a “black box”? Intellectual property protection.
Phase 3: Testing Model in Real World Settings

• **Consent**: Do patients need to consent to have the model used “on them”? Notification when they enter hospital?

• **Liability**: Integration with decision support software may lead to new liability risks. Vicarious liability for health systems?

• **Choice Architecture**: Should the model trigger default care intervention (opt out)?

Phase 4: Broader Dissemination of Model

• **Equitable Access**: Can all health systems that contribute to the model development afford to implement? Graduated licensing fees?
• *Imperfect Implementation*: Can result from poorly constructed work flows, insufficient consideration of patients’ preferences, inadequate checks and balances. Who has liability for “off label” use?

• *The Role of the Physician*: New training requirements and communication challenges. Shift to team-based care. Frequent hand-offs and problem of lack of awareness of patient preferences? Importance of maintaining physician override.
Big Data: Need For New Thinking, Training And Tools

Harlan M. Krumholz, MD, SM
Harold H. Hines, Jr. Professor of Medicine
Yale University School of Medicine

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The Problem

The current medical research enterprise cannot keep pace with the information needs of patients, clinicians, administrators, and policy makers.
The Solution

Data generated every day, for a variety of practical purposes, could serve as an inexhaustible source of knowledge to fuel a learning health care system.
New Thinking...
To embrace inductive reasoning and pattern recognition on an equal basis with deductive reasoning.

New Training...
To invest in strengthening the skills of clinical investigators.

New Tools...
To develop and implement practical methods customized for issues germane to medicine.
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