7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges

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Table of Contents

Meeting Agenda...........................................................................................................................................04
Meeting Overview........................................................................................................................................08
Selected Terms and Terminology .............................................................................................................12
Proposed Principles for Data Use............................................................................................................14
Overarching Meeting Discussion Questions.............................................................................................16
Breakout Session Discussion Questions....................................................................................................17
Breakout Session Guidelines....................................................................................................................19
Sample Data Use Scenarios......................................................................................................................20
Steering Committee, Speaker, Facilitator, and Recorder Biographies....................................................22
Examples of Current Data Use Projects and Activities............................................................................34
Examples of Federal Agency/Organization Data Use Programs and Policies.....................44
AMIA Wishes to Thank the Following Organizations for their Sponsorship and Support of the Meeting

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Astra Zeneca, Deloitte, GE Healthcare, GSK, IBM, Oracle, Philips HealthCare, RTI, and Wolters Kluwer
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Meeting Agenda

Goals

- To further a national understanding of health data use.
- To review principles of data use that can be used to promote an appropriate, effective, informative, and balanced message about the value of health data use.
- To develop an action agenda about how appropriate health data use practices can best be supported by health IT and informatics, including next steps or areas for future research, strategies for implementation and key policy issues.
- To formulate specific recommendations to government, industry, academia, and other stakeholders and identify key steps for moving the action agenda forward.

Day 1 December 12, 2012

7:30 AM  Registration and Continental Breakfast (provided)
Room: Foyer 2

8:00 AM  Welcome and Opening Remarks: Gil Kuperman, AMIA BOD Chair, and Kevin Fickenscher, AMIA President/CEO
Room: South American AB

8:10 - 8:30 AM  Opening General Session: Setting the Stage. George Hripcsak, Steering Committee Chair and Patti Brennan, Vice Chair
Room: South American AB
  - Framing the Meeting/Meeting Assumptions
  - Review of Pre-meeting Work Products ( Briefing Book)
  - Overview of the Day/Meeting Logistics
• Charge to Meeting Presenters and Participants

8:30 - 9:30 AM  
**Plenary Session: Current Activities and Insights**  
*Room: South American AB*  
- Update from the Secondary Data Use SHARP Grant - Chris Chute  
- EU Data Stewardship Framework - Charlie Safran  
- Overview of Relevant AHRQ Activities - Gurbaneet Randhawa

9:30 - 10:00 AM  
**Overview and Goals for Breakout Session 1**  
*Room: South American AB*  
- Describe Purpose of Proposed Principles of Data Use; Acknowledge Draft Use Cases; Introduce Definitions - Patti Brennan  
- Charge to Meeting Participants - George Hripcsak

10:00 - 10:30 AM  
**Break and Participants Travel to Breakout Session 1**  
*Room: Foyer 2*

10:30 - 12:30 PM  
**Breakout Session 1: Demonstrate Value of Data Use**  
*Room: Federal A*  
*Room: Federal B*  
*Room: Pan American*

12:30PM - 1:00 PM  
**Lunch (provided)**  
*Room: South American AB*

1:00 - 2:00 PM  
**Plenary Session: Proposal and a Reactor Panel: Dramatic Reform of National Policy to Support Secure Access to Person-level Data for Quality Life-giving Research**  
*Room: South American AB*  
- Gil Kuperman, Moderator  
- Don Detmer, Presenter  
- Patti Brennan and Soumitra Sengupta, Reactor Panel

2:00 - 2:30 PM  
**Report Outs from Breakout Session 1**  
*Room: South American AB*

2:30 - 2:45 PM  
**Overview and Goals for Breakout Session 2**  
*Room: South American AB*  
- Identify Impediments to Data Use and Foresee Future Challenges - Peter Embi  
- Charge to Meeting Participants - George Hripcsak
2:45 - 3:00 PM  Break and Participants Travel to Breakout Session 2
Room: Foyer 2

3:00 - 5:00 PM  Breakout Session 2: Identify the Major Future Challenges, Gaps and Barriers to Appropriate and Effective Health Data Use
Room: Federal A
Room: Federal B
Room: Pan American

5:00  Day 1 ADJOURN
Participants have dinner on their own

6:00 PM  Steering Committee Dinner/Debrief
Room: Massachusetts Room

Day 2  December 13, 2012

7:30  Registration and Continental Breakfast (provided)
Room: Foyer 2

8:00 - 8:30 AM  Opening Plenary Session: George Hripcsak
Room: South American AB
  •  Review of Day One
  •  Overview of Day 2/Meeting Logistics

8:30 - 9:30 AM  Plenary Session: Considerations for Data Stewardship and Governance
Room: South American AB
  •  Jane Thorpe
  •  Peter Embi

9:30 - 10:00 AM  Report Outs from Breakout Session 2
Room: South American AB

10:00 - 10:15 AM  Overview and Goals for Breakout Session 3
Room: South American AB
  •  Identify and Recommend Actions in the Policy, Regulatory, Research, and Technological Domains to Propel Action - Margo Edmunds
  •  Charge to Meeting Participants - George Hripcsak
10:15 - 10:30 AM  Break and Participants Travel to Breakout Session 3  
Room: Foyer 2

10:30 AM - 12:00PM  Breakout Session 3: The Future: Building on Previous Discussions, Recommend Actions in the Policy, Regulatory, Research and Technological Domains to Propel Action  
Room: Federal A  
Room: Federal B  
Room: Pan American

12:00 PM - 1:00PM  Reports from Breakout Session 3  
Room: South American AB

Large Group Discussion: Where Do We Go from Here? - George Hripcsak  
Room: South American AB

- Identify common themes and potential levers to advance the discussions
- Formulate key messages for policymakers
- Propose next steps and action items for stakeholders

1:00 PM  Concluding Remarks, Thank You, and Acknowledgments - George Hripcsak  
Room: South American AB

Steering Committee Debrief  
Room: South American AB
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Meeting Overview

Purpose of Meeting. The meeting seeks to 1) further a national understanding of health data use in light of new and emerging technology-enabled sources of data, and to promote appropriate, effective use of these data through recommended policy updates and a research agenda; and 2) help develop and advance a nationwide framework for data use that recognizes data as an organizational and enterprise-wide asset and resource with an emphasis on data quality and utility, and acknowledges the significant role of patients, consumers, and caregivers in their health and health care.

Background. In 2006 and 2007, AMIA devoted its Annual Health policy meetings to the topic of use of health data. AMIA noted that use of health data can enhance healthcare experiences for individuals, expand knowledge about disease and appropriate treatments, strengthen understanding about the effectiveness and efficiency of our healthcare systems, support public health and security goals, and aid businesses in meeting the needs of their customers. Yet, access to and use of data still poses complex ethical, political, technical, and social challenges.

AMIA believes that while data use efforts are moving forward, new public policy implications are arising related to data capture and collection, data use and data quality. What constitutes and comprises health data has undergone an evolution over the past five years, and now spans the gamut of data from genomic data collected from individuals to data generated by clinicians and devices in the course of care for an individual person to self-reported observations made by an individual to sensor-generated signals indicating how far a person has walked or their resting sleep patterns. As health care moves from the institution to the home and community, effective clinical decision making and quality of care evaluation will increasingly rely on data
generated across the health lifespan of the individual, and these emerging data types require special consideration. Biomedical and health informatics has developed data models and terminologies to address the first type of data (that generated in the direct course of patient care); however, much work remains to develop formalization tools and governance policies for these and future types.

Furthermore, existing public policies have not been able to keep pace with rapidly emerging technologies (such as the proliferation of devices and mobile applications now collecting, storing, maintaining and reporting health data, and the wider availability of genomic data). It is not clear to what extent the data are sufficiently accurate and consistent to support their varying and multiple uses. New and creative collaborative public-private sector efforts to promote clinical data quality, foster and disseminate best practices for assuring uniformity of policies and practices, and support studies to investigate the reliability and validity of health data may be needed. There are also critical hurdles to the optimal use of digital data for analytics, comparative effectiveness research (CER) and care improvement. These include data quality, data representation, data completeness, data timeliness, governance, technology, privacy, sustainability, and issues of workforce development.

**Meeting Goals**

- To further a national understanding of health data use.
- To review principles of data use that can be used to promote an appropriate, effective, informative, and balanced message about the value of health data use.
- To develop an action agenda about how appropriate health data use practices can best be supported by health IT and informatics, including next steps or areas for future research, strategies for implementation and key policy issues.
- To formulate specific recommendations to government, industry, academia, and other stakeholders and identify key steps for moving the action agenda forward.

Through the 2012 meeting, AMIA seeks to advance discussions and to identify how informatics can help address real and perceived challenges, obstacles and barriers to data use and sharing.
While many public and private organizations are focusing on the topic, each group appears (perhaps too) narrowly focused on only certain aspects of data use; for example, data use for CER; data use for clinical trials; data use for drug development; data use for transitions of care; data use to improve quality; and data use to reduce costs.

The meeting will build on AMIA’s prior work on use of health data in light of new and emerging healthcare game changers: for example, precision and personalized medicine, patient-centered care, heightened emphasis on performance measures and outcomes, and the growing adoption of EHRs. 1 2 In addition, the meeting will leverage the prior and ongoing work of several organizations including the Agency for Healthcare Research and Quality (AHRQ) 3, the Institute of Medicine (IOM) 4 5, the National Committee on Vital and Health Statistics (NCVHS) 6, the Bipartisan Policy Center (BPC) 7, the Office of the National Coordinator for Health Information Technology (ONC) 8, and the Patient Centered Outcomes Research Institute (PCORI) 9.


3 http://www.edm-forum.org/publicgrant/About/projectprofiles/edmforum/


8 http://www.healthit.gov/policy-researchers-implementers

9 http://www.pcori.org/
**Meeting Activities**

- Review and discuss a set of proposed principles of data use.
- Develop an action agenda about how health data use practices can best be supported by health IT and informatics, including next steps or areas for future research, key policy issues and strategies for implementation.
- Formulate recommendations to government, industry, academia, and other stakeholders and identify key steps for moving the action agenda forward.
- Synthesize and disseminate the meeting deliberations, findings, and outcomes in the form of a final report to inform the policymaking process in this domain.

**Meeting Assumptions**

- Despite challenges, data are currently being used for multiple legitimate purposes beyond direct patient care. (See Examples of Current Data Use Projects and Activities)
- Technology impacting health data collection and analysis is moving rapidly while supportive public policies are lagging and/or inconsistent. Challenges are technical, technological, systemic (healthcare system), ethical, and socio/cultural. (See Examples of Federal Government Agency/Organization Data Use Policies and Programs)
- It is necessary to examine the roles and responsibilities of all stakeholders (including patients) with regard to data collection, quality, stewardship and governance.
- Health data are viewed as an organizational and system-wide asset and resource.
- Discussions about the appropriate data stewardship and governance and issues related to data quality are more important than ever.
- Data use will only succeed with the buy-in of the public, and AMIA can assist in creating an informative, succinct, balanced public message.
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting December 12-13, 2012

Selected Terms and Terminology

For the purposes of this meeting, the term “data use” refers to the “re-use” or “continuous use” of data for intentions other than those for which they originally collected. Below are other relevant proposed and previous (AMIA) definitions.

(Proposed) Continuous Data Use

Data collection is expensive in terms of time and money. Use of data should be viewed as “continuous” – and readily available – for patient care, analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities.

- To the extent possible, data should be collected once and used many times (continuously).
- For direct patient care, whenever new data are obtained and added, the patient’s status should be assessed and analyzed using appropriate and available data.
- Data collectors, data stewards and data aggregators must help assure that data are available continuously and of high quality for appropriate query and use.

Previous AMIA Definitions

- **Re-use of health data** occurs when personal health data are used for purposes other than those for which they were originally collected.
- **Data stewardship** encompasses the breadth of activities carried out in varying degrees by all entities that interact with health data, including collection, use, disclosure,

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AMIA Invitational Health Policy Meeting 2012
Page 12 12/10/2012
management and security of that information. Within each of these aspects there are medical-legal, ethical, and best practice considerations that individuals and organizations should consider in the management of health information.

**Previous (AMIA) Descriptors (Attributes) for High Quality Information**

These attributes include high sensitivity (all of the information needed by the patient's care team is created and recorded) and high specificity (information that is not needed by the care team is not displayed); cogency (information is created and recorded in ways to make it easy to read, process, and act on by humans and computers); and actionability (information helps guide the patient's team in executing effective, safe, efficient, and satisfying interventions. Being actionable includes being computable, for example, in clinical prediction rules when appropriate to the patient's needs). While high sensitivity and high specificity are attributes of high quality information, it should also be noted that they are context-dependent. For example, an item of information might be highly useful and should be displayed to a decision maker when a diagnosis is being established, but of lower usefulness and should be hidden when management or disposition is the task at hand. Further refinement of these descriptors is needed to reflect these nuances.

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12 Perspective: The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. Caitlin M Cusack, George Hripcsak, Meryl Bloomrosen, S Trent Rosenbloom, Charlotte A Weaver, Adam Wright, David K Vawdrey, Jim Walker, Lena Mamykina J Am Med Inform Assoc amiajnl-2012-001093Published Online First: 8 September 2012 doi:10.1136/amiajnl-2012-001093
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Proposed Principles of Health Data Use

The principles outlined below refer to data about individuals related to their health and health care that are collected by diverse sources, including electronic health records and remote monitoring. The Meeting Steering Committee developed these principles for reference during the AMIA 2012 policy meeting.

1. Appropriate ongoing use of patient health data beyond clinical care of individuals is essential for the nation as a whole and for individuals in order to achieve better health, and safer, better quality of care. Health data should be available and usable on a continuous basis for various purposes.

2. In order to maximize their utility, health data must be made as trustworthy, timely, accurate, accessible, and reliable as possible, and we must be able to track the degree to which health data have attained these properties.

3. Different people, organizations, and stakeholders have varying perceptions and relationships with data that must be honored in order to achieve the compelling and mutual benefits of health data use.

4. There are growing and divergent needs for health data to address efficacy, safety, and effectiveness of health care. Examples include:

   • Data are needed to promote health improvement and maintenance; disease prevention; treatment targeting and improvement; and reduction of health care costs.
   • Data can help identify, track and address public and population health challenges as well as health issues related to environmental concerns and natural disasters.
   • Data can help improve the health and care of future patients who might have the same or similar conditions.
5. Safeguarding health data from inappropriate use or misuse is essential to assure public support and patient confidence. Those who maintain, aggregate, and use health data, must demonstrate that they are worthy of trust in order to earn and retain the support of patients and the public.

6. There is some risk, however small, of loss or disclosure of confidential patient data. Therefore, in any use of health data, the costs of such loss or disclosure as well as the potential benefits of data use must be carefully assessed.

7. It is not feasible to anticipate all future data sources or data capture technologies and techniques and their potential impact on using data to achieve better health and better quality of care. Thus, healthcare system stakeholders must continue to study the impact of use of health data on research and discovery of new knowledge, quality improvement, public health surveillance, and cost reduction, refining these principles as needed, and continually seeking to achieve an appropriate balance between privacy and security and data use.
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Overarching Meeting Discussion Questions

Participants are asked to consider these overarching questions throughout the meeting.

Given the ongoing and emerging organizational, technical, technological, and political issues, opportunities and challenges related to the integration, availability, and use of data from multiple sources:

- What does the future of health data look like and how do we get there?
- How can we develop and instill a culture that promotes safe and trustworthy “continuous data use?” (See terms and terminology)
- How can we ensure the ongoing accuracy, reliability, and integrity of health and health-related data that are collected, reported and increasingly being used nationally and globally for various purposes?
- With the growing emphasis and acceptance of patients’ role in care, what roles and responsibilities does the patient have regarding data use? Data stewardship?
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Breakout Sessions Discussion Questions

Breakout Session 1: Demonstrate Value of Data Use

1. How can we best illustrate and communicate the value and benefits of data use to patients, providers and other healthcare system stakeholders?

2. What are the risks to patients, the U.S. healthcare system and global stakeholders of not using, exchanging, and sharing data?

Breakout Session 2: Identify the Major Future Challenges, Gaps and Barriers to Appropriate and Effective Health Data Use

1. Identify the most significant future challenges related to data use.
   a. What should patients’ roles and responsibilities be with regard to health data use? How can processes be designed and implemented to ensure patient understanding and build patient confidence? What are the public policy issues and challenges regarding integration of patient-entered/mediated data?
   b. What challenges exist/are emerging about “Big Data?” To what extent are public policies on “cloud data” needed? How can we deal with emerging technical challenges related to increasingly larger and more granular data compendia/compilations?
   c. What are the challenges related to the increased availability and diversity of data sources and the resulting need to integrate these data (such as genomic and molecular data, data from mobile applications, data from medical and implanted devices and sensors) into the EHR?

2. Identify the key challenges regarding data quality. To what extent do all data uses share the same requirements for quality (e.g., timeliness, reliability, and validity)? In what ways are lack of (or inconsistent) standards impeding data use efforts?
Breakout Session 3: The Future: Building on Previous Discussions, Recommend Actions in the Policy, Regulatory, Research and Technological Domains to Propel Action

1. How can we address the emerging and future challenges to appropriate and effective data use? Examples of approaches include: changes in government policies/regulations (central, regional, state or local level) and/or new ones; development and widespread adoption of data stewardship principles and creation of a culture of continuous data use; voluntary oversight; collaboration (public/private) on data standards; collaboration with and education of patients/consumers.
   a. For each challenge identify the proper level(s) for action such as federal, state, industry, and consumer.
   b. What additional research is needed to address the identified gaps and challenges?

2. What are the best ways to inform and educate stakeholders about the value and benefits of data use? How can AMIA assist in creating an informative, succinct, balanced public message about the value and benefits of appropriate data use?
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012
Guidelines for Breakout Sessions

• The designated facilitators are in charge of the process.
• All ideas and opinions are welcome, valid, and respected. Every idea from every source has equal weight.
• Be clear and brief.
• It's OK to disagree.
• Ambiguity is OK.
• Both/all sides of a position are acceptable.
• There may be no consensus or solution.
• Everyone participates, no one dominates.
• Maintain an open and positive attitude.
• Be non-defensive about your own ideas.
• Stay focused on meeting themes, purposes, and outputs.
• Everyone participates
• Build on an idea—if possible
• Look for relationships between/among ideas
• Give an example to clarify what you mean
• Both/all sides of a position are acceptable. There may be no consensus or solution to opposing ideas in a brainstorming session.
• Stay focused on the brainstorming theme.
• Think outside the box
• Suspend criticism and evaluation
• Avoid side conversations.
• Please stay to the end.
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012
Sample Data Use Scenarios

Introduction

Use of health data from electronic health records (EHR) and from other sources will only succeed with general public support. However, the topic is complex and the public is receiving mixed extreme messages: unrealistic visions of the potential and short timeline for use of EHR data as well as unwarranted and pessimistic views of the challenges and dangers of data use.

One of the goals of the 2012 AMIA meeting is to develop recommendations for a strategy to inform the public about the reasonable and feasible benefits of appropriate data sharing and use. The strategy could include both the message and how best to deliver it.

It may include scenarios such as those listed below, which are adapted from the May 2012 European Summit on Trustworthy Reuse of Health Data (http://www.imia-medinfo.org/new2/node/357). The strategy can also include information about how health data are being used today, as well as helpful analogies to other fields. The strategy should focus less on whether data use and sharing should occur and more on how and when.

- **Scenario 1 (adapted from the EU conference).** Children with attention deficit-hyperactivity disorder (ADHD) are frequently treated with medications that have stimulant effects on the heart. Although these medications are generally thought to be safe, case reports from Canada and the U.S. included cases of sudden death, heart attacks, and strokes in children under treatment for ADHD. A retrospective analysis of multiple data sources including EHRs, health registries, and pharmacies providing data for 1,200,438 children ages 2 to 24 was conducted to determine the risk of cardiovascular events for children taking ADHD medications. (This scenario is adapted from an article in the *New England Journal of Medicine*.13) Many believe that large

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clinical databases are necessary to provide evidence-based recommendations for rare diseases. This scenario also stresses the need for large data sets to analyze rare outcomes in relatively common clinical situations. This type of analysis is not real time, but involves the integration of multiple data sources that may not share any standards.

- **Scenario 2 (adapted from the EU conference).** There is a new strain of Flu that has surfaced in China. There is growing concern that it will spread throughout the world given the increase in trade and interaction with all parts of Asia, coupled with the fact that there are many flights each day into the U.S. The CDC uses a bio-surveillance system that can aggregate all of the chief complaints and other clinical data from every emergency room across the country, monitoring the information streams for “hot spots.” This scenario possesses many potential technical and logistic problems. The data needs to be transmitted real-time and up-front standards need to be in place. This undertaking has consumed over $250 million in the U.S., and still much work remains.
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Steering Committee, Speaker, Facilitator, and Recorder Biographies

Meryl Bloomrosen, MBA, is AMIA’s Vice President for Public Policy and Government Relations. Ms. Bloomrosen has extensive experience leading policy development, strategic advocacy and program implementation at the state and federal levels. At AMIA, Ms. Bloomrosen oversees government relations and public policy activities. Prior to her position with AMIA, Ms. Bloomrosen was a Vice President at the eHealth Initiative (eHI) and the Program Manager of the Connecting Communities for Better Health Program, where she created, executed and managed initiatives such as a HRSA-funded, multimillion dollar cooperative agreement involving regional health information organizations. She was a senior policy analyst at the Prospective Payment Assessment Commission (ProPAC-now MEDPAC) where she researched topics such as DRGs, severity and risk adjustments and quality of care. She has a certificate in Health Information management from the U.S. Public Health Service, an MBA in Information Systems from George Washington University and a Graduate Certificate in Biomedical Informatics from the Oregon Health & Science University, where she is finishing her masters in Biomedical Informatics. She has also completed the Medical Informatics MBL/NLM Course Fellowship program at the Marine Biological Laboratory, Woods Hole, MA.

Patricia Flatley Brennan, MSN, PhD, is the Lillian L. Moehlman Bascom Professor, School of Nursing and College of Engineering, University of Wisconsin-Madison, Madison, Wisconsin. Dr. Brennan received an MS, Science in Nursing from the University of Pennsylvania and a PhD in Industrial Engineering from the University of Wisconsin-Madison. Following seven years of clinical practice in critical care nursing and psychiatric nursing, Dr. Brennan held several academic positions. She developed the ComputerLink, an electronic network designed to reduce isolation and improve self-care among home care patients and directed HeartCare, a WWW-based tailored information and communication service that helped home-dwelling cardiac patients recover faster, and with fewer symptoms. Dr. Brennan is National Program Director of Project HealthDesign, a RWJ-funded initiative designed to stimulate the next generation of personal health records. Additionally, she oversees the external evaluation of the SMArt initiative, a novel, distributed health information architecture that brings the power of an “Apps-store” model to electronic health records. Dr. Brennan leads the Living Environments
Laboratory at the Wisconsin Institutes for Discovery, which includes a 6-sided virtual reality CAVE that her group uses to re-create visually every environment on earth, and develop new ways for effective visualization of high dimensional data. She is a fellow of both the American Academy of Nursing (1991) and the American College of Medical Informatics (1993). Dr. Brennan was elected to the Institute of Medicine in 2002, and in 2009 became an elected member of the New York Academy of Medicine.

Christopher G. Chute, MD, DrPH, received his undergraduate and medical training at Brown University, internal medicine residency at Dartmouth, and doctoral training in epidemiology at Harvard. He is board certified in Internal Medicine, and a Fellow of the American College of Physicians, the American College of Epidemiology, and the American College of Medical Informatics. He became founding Chair of Biomedical Informatics at Mayo Clinic in 1988, and is PI on a large portfolio of research. He is presently Chair, ISO Health Informatics Technical Committee (ISO TC215) and Chairs the World Health Organization (WHO) ICD-11 Revision. He also serves on the Health Information Technology Standards Committee for the Office of the National Coordinator in the U.S. Department of Health and Human Services, and the HL7 Advisory Board.

James Cimino, MD, is a board certified internist who completed a National Library of Medicine informatics fellowship at the Massachusetts General Hospital and Harvard University and then went on to an academic position at Columbia University College of Physicians and Surgeons and the Presbyterian Hospital in New York. He spent 20 years at Columbia, carrying out clinical informatics research, building clinical information systems, teaching medical informatics and medicine, and caring for patients, rising to the rank of full professor in both Biomedical Informatics and Medicine. In 2008, he moved to the National Institutes of Health, where he is the Chief of the Laboratory for Informatics Development and a Tenured Investigator at the NIH Clinical Center and the National Library of Medicine. His principal project involves the development of the Biomedical Translational Research Information System (BTRIS), an NIH-wide clinical research data resource. In addition, he conducts clinical research informatics research, directs the NLM’s postdoctoral training program in clinical informatics, participates in the Clinical Center’s Internal Medicine Consult Service, and teaches at Columbia University as an Adjunct Professor of Biomedical Informatics. He is a Fellow (and currently President) of the American College of Medical Informatics, the American College of Physicians, the American Clinical and Climatological Association, and the New York Academy of Medicine.

Don E. Detmer, MD, MA, FACS, is Medical Director for Advocacy and Health Policy of the American College of Surgeons. He is also Professor Emeritus and Professor of Medical Education at the University of Virginia and Visiting Professor at CHIME, University College of London. Dr. Detmer was appointed as President and CEO of the American Medical Informatics Association from 2004 until 2009 when he became Senior Advisor to AMIA until 2011. Dr. Detmer’s education includes a medical degree from the University of Kansas with subsequent training at the National Institutes of Health, the Johns Hopkins Hospital, Duke University Medical Center, the Institute of Medicine, and Harvard Business School. His MA is from the University of Cambridge. Don Detmer is a former trustee of the Nuffield Trust; a member of the Institute of Medicine (IOM) as well as a lifetime Associate of the U.S. National Academies, a fellow of AAAS, and the American Colleges of Medical Informatics, Sports Medicine, and Surgeons. He founded
the Blue Ridge Academic Health Group and co-chaired it through 2011. He chairs the board of Medbiquitous. Dr. Detmer is past chairman of the Board on Health Care Services of the IOM, the National Committee on Vital and Health Statistics, and the Board of Regents of the National Library of Medicine. He was a Commissioner on the Commission on Systemic Interoperability. Dr. Detmer chaired the 1991 study, "The Computer-based Patient Record". He was a member of the committee that developed the IOM Reports, "To Err is Human" and "Crossing the Quality Chasm." From 1999-2003 he was the Dennis Gillings Professor of Health Management at Cambridge University and is a lifetime member of Clare Hall College, Cambridge.

**Brian E. Dixon, PhD, MPA, FHIMSS**, is Assistant Professor of Health Informatics, IU School of Informatics at Indiana University-Purdue University of Indianapolis; Research Scientist, Indiana University Center for Health Services and Outcomes Research; Research Scientist, Centers for Health Services Research and Biomedical Informatics, Regenstrief Institute, Inc.; and Investigator in Residence, VA HSR&D Center of Excellence on Implementing Evidence-Based Practice. Dr. Dixon’s research focuses on developing and evaluating innovative technologies and processes for managing knowledge regarding individual patients and populations. His recent work has involved leveraging health information exchange (HIE) to enable secondary use of clinical and administrative data for improving public health surveillance, continuity of care for veterans, the determination of disability, and clinical decision support. Before joining the faculty at Indiana University, Dr. Dixon managed research and development projects for Regenstrief and the Indiana Health Information Exchange. Dr. Dixon also developed health information applications and systems, including tools supporting the standard clinical vocabulary LOINC®, technology supporting the automated reporting of notifiable conditions to public health agencies, and tools for querying large clinical data repositories. Dr. Dixon earned his Bachelor of Arts in computer science from DePauw University; his Master of Public Affairs from Indiana University; and his Doctor of Philosophy in Health Informatics from Indiana University.

**Margo Edmunds, PhD**, is Vice President, Evidence Generation and Knowledge Translation, at AcademyHealth. She has more than twenty years experience leading health information and communications technology projects and policy initiatives for federal and state government, foundations, associations, and other clients. She chairs the AMIA Public Policy Committee, is a founding member and former chair of the Health IT Interest Group at AcademyHealth. She recently joined the editorial board of *Applied Clinical Informatics* and is a reviewer for the *International Journal of Medical Informatics*. Dr. Edmunds earned her doctoral degree in community/clinical psychology from The Pennsylvania State University. She completed a post-doctoral fellowship at the Johns Hopkins School (JHS) of Public Health and was a Research and Clinical Fellow and Instructor of Medical Psychology in the JHS of Medicine. Dr. Edmunds recently directed a Congressionally-requested Institute of Medicine study on Medicare hospital and physician payment. Previously, she was Vice President at The Lewin Group, Health IT team strategist at Booz Allen Hamilton, Director of the Health Division at the Children’s Defense Fund, and Adjunct Associate Professor of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. She is a Fellow and former member of the Board of Directors of the Society of Behavioral Medicine. Her published work includes online commentary, media backgrounders, technical reports, white papers, issue briefs, and books.
Peter J. Embi, MD, MS, FACP, FACMI, is Associate Professor of Biomedical Informatics and Internal Medicine (Rheumatology), and Vice-Chair of the Department of Biomedical Informatics at The Ohio State University. He serves as Chief Research Information Officer for The Ohio State University Wexner Medical Center (OSUWMC), a role that provides him oversight of the IT environment for research at OSUWMC. Dr. Embi is also co-Director of the Biomedical Informatics Program for the NIH-CTSA-funded OSU Center for Clinical and Translational Science. As an NIH-funded investigator focused on the field of Biomedical Informatics, Dr. Embi is internationally recognized for his expertise, particularly in the area of Clinical Research Informatics. He has held various leadership roles in AMIA, and served as scientific program chair for the first-of-its-kind AMIA Summit on Clinical Research Informatics in 2010. In recognition of his efforts to advance this sub-domain of biomedical informatics, he was awarded the AMIA leadership award in 2011. He is also active in the leadership of the American College of Rheumatology (ACR), having served on the Board of Directors from 2008-2010 and now serving as chairperson of the ACR's Registries and Health IT committee. Dr. Embi earned his MD from the University of South Florida, completed Internal Medicine and Medical Informatics training at the Oregon Health & Science University, and completed a second fellowship in Rheumatology & Immunology at the Cleveland Clinic. Prior to joining the faculty at The Ohio State University, Dr. Embi was Associate Professor of Medicine and Director of the Center for Health Informatics at the University of Cincinnati, where he also served as the first director of Biomedical Informatics for the NIH-CTSA-funded Cincinnati Center for Clinical and Translational Science and Training.

Kevin M. Fickenscher, MD, CPE, FACPE, FAAFP, serves as the President and CEO of AMIA. Prior to joining AMIA, he served in a variety of domestic and international positions for Dell Healthcare Services, primarily through the company’s acquisition of Perot Systems where Dr. Fickenscher served as the Chief Medical Officer and leader of the healthcare information technology consulting practice. He led the organization’s International Healthcare practice and extended operations into the Middle East, India, China and Latin America. He was the Chief Medical Officer at WebMD, and then served as Director of Clinical Transformation at Computer Sciences Corporation (CSC), before joining Perot Systems. Prior to his healthcare information technology focus, Fickenscher served in several administrative healthcare leadership roles, as Senior Vice President and Chief Medical Officer for two of the premier integrated healthcare systems in the nation—Aurora Health Care and Catholic Healthcare West. Dr. Fickenscher was an Assistant Dean with Michigan State University College of Human Medicine where he developed the Center for Applied Medical Informatics. He served as the Founding Director of the Center for Rural Health, University of North Dakota School of Medicine and Health Sciences. Dr. Fickenscher has also served as adjunct and associate professors at several universities and colleges. Dr. Fickenscher graduated from the University of North Dakota, School of Medicine and Health Sciences in 1978 and trained as a family physician. He obtained his Family Practice Board Certification in 1982.

Melissa M. Goldstein, JD, is an Associate Professor in the George Washington University School of Public Health and Health Services, where she teaches courses in bioethics, health information technology policy, and public health law and conducts research on the legal and policy aspects of health information technology. Ms. Goldstein is a former director of the
Markle Foundation’s health program, where she managed the policy subcommittee of Connecting for Health and other policy aspects of the foundation’s work in health information technology. Ms. Goldstein also worked as a legal consultant to President Clinton’s National Bioethics Advisory Commission, a senior litigation associate at Skadden, Arps, Slate, Meagher, and Flom, LLP, and a White House Fellow and domestic policy advisor to Vice President Al Gore. Ms. Goldstein graduated Phi Beta Kappa from the University of Virginia, received her law degree from Yale Law School, and completed a post-doctoral fellowship in bioethics and health policy at Johns Hopkins and Georgetown Universities. She has served as a member of GW’s IRB and hospital ethics committee and speaks frequently on issues in bioethics, health policy, and health information technology. Ms. Goldstein’s recent research and writings have focused on privacy and security issues in health information exchange and the effects of health information technology on the physician-patient relationship and consumer engagement. During the 2010-2011 academic year, she served as a senior advisor to the Chief Privacy Officer in the Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

**W. Ed Hammond, PhD**, is Director of the Duke Center for Health Informatics; Associate Director of the Bioinformatics Core, Duke Translational Medicine Institute (DTMI); and Director of Applied Informatics Research, Duke Health Technology Solutions (DHTS). The Center has the responsibility for teaching and training and brings together informatics interests across the institution. His positions in DTMI and DHTS bring together interests in clinical research and operations. Dr. Hammond’s degrees are in Electrical Engineering with two years post-doctoral training in Medicine. He led a team that developed one of the first computer-based patient records (TMR), beginning in 1970. TMR was implemented in 42 settings nationally. He was one of the founders of HL7 in 1987, has served as chair three times, and is currently secretary for the HL7 Board. He has also been involved in international standards activities and has served in several leadership roles in many national informatics organization including SIGBIO, CPRI, AMIA, and ACMI. His current activities at Duke bridge the gap from the ‘omics to population health, including clinical research, clinical patient care, primary care and the medical home, and public health. His interests are focused on data: data warehouse, smart data elements, data quality, data provenance, data sharing, and data governance.

**Courtney L. Hebert, MD** is a post-doctoral researcher in the Department of Biomedical Informatics at the Ohio State University Wexner Medical Center. In addition to her work with the informatics department she continues to work as an infectious diseases physician as part of the Division of Infectious Diseases and is pursuing her Master’s in Public Health with a specialization in biomedical informatics. Her research interests are in using data captured in the electronic health record (EHR) for disease surveillance and risk modeling. Her post-doctoral research focuses on using EHR data to predict hospital readmissions.

**George Hripcsak, MD, MS**, is Vivian Beaumont Allen Professor, and Chair of Columbia University’s Department of Biomedical Informatics and Director of Medical Informatics Services for New York-Presbyterian Hospital. Dr. Hripcsak is a board certified internist with degrees in chemistry, medicine, and biostatistics. He led the effort to create the Arden Syntax, a language for representing health knowledge that has become a national standard. Dr. Hripcsak’s current research focus is on the clinical information stored in electronic health records. Using data...
mining techniques such as machine learning and natural language processing, he is developing the methods necessary to support clinical research and patient safety initiatives. As Director of Medical Informatics Services, he oversees a 7000-user, 2.5-million-patient clinical information system and data repository. He is currently co-chair of the Meaningful Use Workgroup of the Department of Health and Human Services’ (DHSS) Office of the National Coordinator of Health Information Technology; the Workgroup defines the criteria by which healthcare providers collect incentives for using electronic health records. Dr. Hripcsak was elected fellow of the American College of Medical Informatics in 1995 and served on the Board of Directors AMIA. As chair of the AMIA Standards Committee, he coordinated the medical informatics community response to the DHHS for the health informatics standards rules under the Health Insurance Portability and Accountability Act of 1996. Dr. Hripcsak chaired the National Library of Medicine’s Biomedical Library and Informatics Review Committee, and he is a fellow of the American College of Medical Informatics and the New York Academy of Medicine. He has published over 200 papers. Dr. Hripcsak was elected to the Institute of Medicine in 2012.

Gail M. Keenan, PhD, RN, is Associate Professor, Department of Health Systems Science and Director, Nursing Informatics Initiative at the UIC College of Nursing. Dr. Keenan’s research focuses on developing and refining a feasible automated methodology for collecting a standardized clinical data set for the purpose of improving the planning, delivery, cost and health outcomes of nursing care across the continuum. Dr. Keenan has served in a variety of regional, national, and international professional roles related to nursing and health informatics. Most recently, she served as the Chair of the American Nurses Association (ANA) Committee on the Nursing Practice Information Infrastructure and was Chair of the American Medical Informatics Association (AMIA) – Clinical Information Systems Work Group. She is currently serving as a member of AMIA’s National Public Policy Committee on health informatics. She is a founding member and UIC College of Nursing Liaison to the CIC Nursing Informatics Research Consortium. This consortium’s core members include nursing informatics faculty from the University of Minnesota, University of Wisconsin (Madison), Indiana University (Indianapolis) and UIC.

Linda L. Kloss, MA, RHIA, is president of Kloss Strategic Advisors, Inc., working with boards and senior teams on information asset management and governance, strategy and change leadership. She writes and speaks on transforming health information management and improving information governance practices. She is currently a member of the National Committee on Vital and Health Statistics, serving as co-chair of its Privacy, Security and Confidentiality Subcommittee. Ms. Kloss served as CEO of the American Health Information Management Association (AHIMA) from 1995 to 2010 and contributed to a number of initiatives to advance health IT as national policy, standards, financial incentives, classifications and vocabularies, and IT use cases. AHIMA was one of three founders of the Certification Commission for Health IT (CCHIT) and Ms. Kloss chaired its board of trustees. She was executive sponsor for a three year grant project from the ONC to identify best practices in state level health information exchange and one on strategies for fraud management with EHRs. In collaboration with AMIA, Ms. Kloss advanced policy issues relating to health informatics and information management workforce development, privacy practices and coordination and
dissemination of vocabularies and classifications. Earlier in her career, Ms. Kloss served as senior vice president for MediQual Systems, Inc. and InterQual Inc., companies that pioneered health data analytics and quality and utilization management. She holds a Master's degree in organizational development with a focus on change management and a baccalaureate degree in health information management.

Gil Kuperman, MD, PhD, FACMI, AMIA Board of Directors Chair (2012-2013), is the Director for Interoperability Informatics at NewYork-Presbyterian Hospital in New York City. His role is to help the hospital realize the benefits of interoperability internally, with its business partners and through participating in regional data interchange efforts. Dr. Kuperman serves as the informatics lead on the hospital’s Medicaid “health home” project and he is the hospital’s representative to Healthix, the health information organization (RHIO) that serves Manhattan and other parts of New York. Dr. Kuperman is the Information Systems representative to the hospital’s strategic Care Coordination Steering Committee. Dr. Kuperman was Chair of the Scientific Program Committee for AMIA in 2010. Previously, Dr. Kuperman served as Board Chair and Executive Director of NYCLIX, a RHIO in New York City. He also was NewYork-Presbyterian Hospital’s Director for Quality Informatics. Dr. Kuperman is an author on over 75 articles. He is a faculty member in the Department of Biomedical Informatics at Columbia University.

Steven Labkoff, MD, FACP, is currently Head of Strategic Programs in AstraZeneca’s Research & Development Information Department. There he leads three teams, Real World Evidence and Payer Evidence, Personalized Medicine and Biomarkers, and Clinical Trials Design and Interpretation, dedicated to leveraging healthcare data for the development of ethical pharmaceuticals. Previously, he was a Senior Manager in Deloitte Consulting’s Healthcare Informatics Practice. Prior to Deloitte, he was with Pfizer Pharmaceuticals for 13 years. His last role was Medical Executive in the Medical Affairs group in Pfizer’s Primary Care Business Unit working with Pfizer’s largest Managed Markets customers. In 2003, he founded and led the Healthcare Informatics Group (HCI) at Pfizer. Previously, Dr. Labkoff was an instructor of Medicine and Medical Informatics at Brigham and Women’s Hospital, Harvard Medical School. He completed a post-doctoral fellowship at Harvard Medical School and Massachusetts Institute of Technology in Medical Informatics. He did a cardiology fellowship at the University for Medicine and Dentistry of New Jersey, his internal medical training at the University of Pittsburgh and at the Albert Einstein Medical Center in Philadelphia. He is an active member of the American Medical Informatics Association where he is Finance Committee chair; the Health Information Management Systems Society; the eHealth Initiative and several other professional organizations. He is a fellow of the American College of Physicians.

Devi Mehta, JD, graduated from the George Washington University in 2003 with a BA in Political Science and Economics. She attended law school at Rutgers-Newark School of Law, and received her JD in 2006. In 2010, she started a Master’s in Public Health Program in Health Policy at the George Washington University’s (GWU) School of Public Health and Health Services. She will receive her MPH in December, 2012. She currently works in the GWU Department of Health Policy as Senior Research Associate. Her work involves the management
and writing for the Health Information & the Law website. Her interests include health information technology related to health disparities and privacy of health information.

Megan Martin, BSN, RN is a Masters student in Nursing at the University of Illinois Chicago, concentrating in Nursing Administration and Health Informatics. Megan currently works for Advocate Medical Group as a Clinical Coordinator. She is a member of Sigma Theta Tau and the American Medical Informatics Association.

Shawn Murphy, MD, PhD, developed and has directed the Research Patient Data Registry (RPDR) for Partners Health Care System, beginning in 1999; this information resource allows human studies investigators to access vast amounts of aggregate patient clinical data. Dr. Murphy has served as director of the pharmacovigilance project for Partners since 2007 and Medical Director Research Computing for Partners since 2008. He assumed all responsibility at Partners for oversight of the research computing network which includes development and support for genetics and genomics at the Partners Center for Personalized Genetic Medicine; development and support of tissue sampling and banking; development and support of cluster and other high performance computing; and the continued development and support of RPDR, Informatics for Integrating Biology and the Bedside, and the Pharmacovigilance platforms at Partners.

Douglas Peddicord, PhD, is President of the Washington Health Strategies Group and provides lobbying and government relations services to a variety of health-related organizations. Following a career as a clinical psychologist, he came to Capitol Hill as an American Association for the Advancement of Science (AAAS) Congressional Fellow in 1994. Having been involved with health information policy issues – from privacy, interoperability and HIT implementation to EHRs, PHRs and the evolution of a national health information infrastructure – ever since, Dr. Peddicord has represented AMIA in Washington since 1997.

Gurvaneet Randhawa, MD, MPH, works in the Center for Outcomes and Evidence (COE) at the Agency for Healthcare Research and Quality (AHRQ). He is the program officer on all AHRQ grants that will build and enhance clinical electronic data infrastructure to collect and evaluate prospective, patient-centered outcomes for comparative effectiveness research (CER) focusing on AHRQ priority conditions and populations. These grants are part of four programs: scalable distributed research networks, enhanced registries for quality improvement and CER, PROSPECT, and Electronic Data Methods Forum (http://www.edm-forum.org). These projects will develop electronic clinical infrastructure with the potential capability of performing several functions: CER, quality improvement, disease surveillance and clinical decision support. Dr. Randhawa also provides scientific direction to clinical genomics-related projects conducted by different AHRQ programs. He is interested in research to improve capabilities of the existing electronic clinical data infrastructure in order to clarify the added value of new diagnostics and therapeutics. He has overseen the development of many Evidence-based Practice Center (EPC) reports that systematically and comprehensively clarified the existing evidence on questions of interest to different audiences, including the U.S. Preventive Services Task Force (USPSTF) and the EGAPP working group. He is a past director of the USPSTF program. He has provided programmatic guidance and oversight to the DARTNet project that focused on distributed research in ambulatory care. Prior to joining AHRQ, Dr. Randhawa completed his Preventive
Medicine residency at Johns Hopkins University and his Internal Medicine internship at University of Pennsylvania. Dr. Randhawa also has trained for 9 years in molecular research in two clinical areas, genomic applications in tuberculosis control and in cancer molecular genetics, at two different institutions, Johns Hopkins at Baltimore, Maryland, and M.D. Anderson Cancer Center at Houston, Texas.

Caryn Roth is pursuing her Master's in Public Health in Biomedical Informatics at the Ohio State University (OSU) while working as a research administrator in the Department of Biomedical Informatics. Prior to joining OSU, Ms. Roth graduated from the University of California, Los Angeles with a BS in Computational and Systems Biology and worked as a Public Health Associate for the Centers for Disease Control and Prevention.

Charles Safran, MD, MS, Associate Clinical Professor of Medicine, Harvard Medical School, is a primary care internist who has devoted his professional career to improving patient care through the creative use of informatics. He is currently an Associate Clinical Professor of Medicine at Harvard Medical School and on the staff of the Beth Israel Deaconess Medical Center in Boston, Massachusetts. He is past President and Chairman of the American Medical Informatics Association and was previously Vice-President of the International Medical Informatics Association. He was elected a fellow by the American College of Medical Informatics and the American College of Physicians. Dr. Safran is co-Editor of the International Journal of Medical Informatics and on the Health on the Net (HON) Foundation Council. He was appointed by the White House to the Consumer Empowerment workgroup of the American Health Information Community. He has helped develop and deploy large institutional integrated clinical computing systems, ambulatory electronic health records, and clinical decision support systems to help clinicians treat patients with HIV/AIDS and personal care support systems for parents with premature infants which he calls collaborative healthware. He founded a company, Clinician Support Technology and as its CEO successfully brought his ideas to a national market. The company’s products and technology were acquired by a major public company. He has over 150 publications and has recently testified for the U.S. Congress on Health IT. He graduated cum laude in Mathematics and hold a Masters degree in mathematical logic and a Doctor of Medicine, all from Tufts University.

Soumitra Sengupta, PhD, is Associate Clinical Professor in the Department of Biomedical Informatics at Columbia University, and is the Information Security Officer at the NewYork-Presbyterian Hospital and the Columbia University Medical Center in New York. He has a PhD in Computer Science from the State University of New York, Stony Brook. In the past 25 years, he has worked in networking, network and systems management, clinical information exchange, web-based access to clinical records, and information security in the context of a tertiary care environment with direct operational responsibility for these services. His operational and research interests are in the areas of derivation of anomalies and access roles from audit logs, security analytics in healthcare computing, and complex identity management systems.

Stuart Speedie, PhD, is a Professor of Health Informatics and a Fellow in Minnesota’s Institute for Health Informatics at the University of Minnesota where he serves as Co-Director, and Director of Graduate Studies. He is also an Honorary Professor of e-Health at King’s College
London. He holds a BS in Computer Science and a PhD in Educational Research from Purdue University and is a Fellow in the American College of Medical Informatics. He is currently Chair of AMIA’s Academic Forum and represents the University of Minnesota on the Minnesota eHealth Initiative. He directs the Great Plains Telehealth Resource and Assistance Center which provides technical assistance to healthcare providers who are establishing telehealth programs. His research activities focus on taking advantage of existing clinical data in electronic health records to improve the efficiency and effectiveness of clinical care. He is actively engaged in evaluations of the impact of HIT on patient and provider outcomes both in primary care settings involving eprescribing and in the ED in the inpatient setting.

Howard Strasberg, MD, MS, is the VP of Medical Informatics for Wolters Kluwer Health – Clinical Solutions. He focuses on clinical decision support, including medication safety screening, reducing alert fatigue and integrating medical knowledge with EHRs. He is also actively involved in standards development as a co-chair of the HL7 CDS working group, which develops CDS standards in areas such as Infobuttons, Order Sets, and Decision Support Services. Dr. Strasberg is also the current chair of AMIA’s Industry Advisory Council. Prior to joining Wolters Kluwer Health in 2003, he was CEO of Skolar, Inc., an online provider of clinical information and continuing medical education (CME) for medical professionals. Dr. Strasberg received his MD degree from the University of Western Ontario and his MS degree in Biomedical Informatics from Stanford University. He is board certified in Family Medicine.

Freda Temple, MLS, has served as a consultant to AMIA since 2006, assisting AMIA staff in editing manuscripts for publication, and in planning and implementing meetings sponsored by the organization. Ms. Temple has over 30 years of professional experience in the fields of health education, information management and communication. As a senior manager at Aspen Systems Corporation, she managed large, multi-faceted AIDS and cancer education programs for the Centers for Disease Control and Prevention, the National Institutes of Health, and the World Health Organization. She is an experienced technical writer with expertise in translating technical information into reader-friendly language for print and web products. Her publications include reports, articles, white papers, manuals, conference materials, briefing books, strategic plans, proposals and marketing materials. She received a Masters in Library Science from the University of Michigan.

Jill DeGraff Thorpe, JD, is General Counsel and Vice President for Strategic Initiatives for AFrame Digital, a health IT company delivering advanced telemonitoring capabilities drawn from discreet observations of daily living. Ms. Thorpe provides thought leadership to executives of healthcare providers in senior living, long-term care, rehabilitation, primary care and home health, and strategic consulting to advance adoption of innovative care delivery and payment models. She also works to establish research demonstrations of the effectiveness of care coordination models. Ms. Thorpe brings over 20 years’ experience advising public and private companies in corporate, strategic partnering, M&A, structured finance, technology acquisition and private equity transactions. Previously, Ms. Thorpe was Associate General Counsel for CyberCash, an early pioneer in secure online payment processing. Before that, she practiced law at Morrison & Foerster, specializing in corporate, securities and financial transactions. She
holds a BA cum laude from Wellesley College, a certificate in health policy from George Washington University, and a JD from The University of Virginia School of Law.

**Jane Hyatt Thorpe, JD,** is an Associate Professor in the Department of Health Policy in the School of Public Health and Health Services at the George Washington University. She specializes in healthcare law and policy in the areas of Medicare, Medicaid, healthcare delivery systems and financing, health information technology, and corporate compliance. Ms. Thorpe also serves as the program director for the Healthcare Corporate Compliance Graduate Certificate Program. Prior to joining the Department in February 2009, Ms. Thorpe served as the Deputy Director of the Office of Policy for the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services. In that role, she was responsible for matters related to the Agency’s crosscutting policy and strategic planning particularly focusing on emerging issues in healthcare delivery and financing. Her previous experience includes policy development and serving as a regulatory liaison to CMS in her role as Associate Vice President for Payment and Policy at the Advanced Medical Technology Association (AdvaMed). Prior to joining AdvaMed, Ms. Thorpe practiced healthcare law. She has an AB magna cum laude in History and a Certificate in American Studies from Princeton University and a JD from Vanderbilt University School of Law. She is a member of the American Health Lawyers Association and the D.C. Bar Association.

**Adam Wilcox, PhD,** is an Associate Professor of Biomedical Informatics at Columbia University, and the Director of Clinical Databases at NewYork Presbyterian Hospital (NYP). He has been involved in many health information technology, exchange, and research efforts in Washington Heights, including NewYork Care Connect. In 2010, he became principal investigator of a $9M award from AHRQ to build an informatics infrastructure for comparative effectiveness research. Prior to his work at Columbia and NYP, he was one of the principal designers of Intermountain Healthcare’s next generation clinical information system.

**Laura Wiley** is a doctoral student in human genetics at Vanderbilt University pursuing a concurrent Master’s degree in biomedical informatics. Research areas include translational genomics and development of algorithms to identify complex phenotypes from electronic medical records. She is currently a member of AMIA's Public Policy Committee.
Health Data Use, Stewardship, and Governance: Ongoing Gaps and Challenges
7th Annual AMIA Invitational Health Policy Meeting
December 12-13, 2012

Examples of Current Data Use Projects and Activities

This matrix highlights selected case studies that feature various examples of data use and data sharing activities. They include federal and state government projects; public/private collaborations; university-based projects; programs managed by research consortia, regional collaboratives, federated networks, and integrated health systems; a multi-drug company initiative; and projects working with non-traditional data sources. The information for many of the entries in the matrix was obtained directly from project representatives who responded to AMIA requests for this information or the information was collected directly from the projects’ websites. These projects are intended as examples of the many data use and data sharing efforts in progress today in the fields of comparative effectiveness research, healthcare quality improvement and cost reduction, and public health monitoring and improvement. The inclusion of several projects focusing on non-traditional data is intended to provide a hint of the intriguing potential of new data sources such as mobile apps and social media that engage patients and consumers in their own health care, and take advantage of real-time, patient-entered/patient-generated data in the pursuit of research.

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<tr>
<th>Project Overview</th>
<th>Purpose/Type of Data</th>
<th>Project Features</th>
<th>Results</th>
<th>Challenges</th>
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| OMOP. Observational Medical Outcomes Partnership. | Data management & computational infrastructure. Methodological research on effective analysis of EHR data to study effects of medical products. Claims and EHR data (de-identified); 80 million patients. | Focus on harmonization of disparate data. Makes available tech tools: library of health outcomes and methods, standard vocabulary, data characterization tools. | Facilitates methodological research by enabling methods that can be applied to produce comparable results across different data sources. Building community of experts leading development of open source analytic framework for data model/vocabulary mappings. | - Limited availability of staff trained in medical vocabularies, data standards  
- Many vocabulary standards exist in data sources and mapping strategies are needed  
- Secondary use of vocabularies presents licensing challenges |
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| **Regional Infection Prevention Collaborative to Reduce (MRSA) Infections.** Indiana Univ/Regenstrief Inst. Regional collaborative to identify and spread effective strategies for MRSA reduction. Funding from AHRQ. | Use of EHR/HIE data to help prevent MRSA infection. (One aspect of comprehensive prevention program). | Use electronic data from regional HIE to identify admitted patients with prior evidence of MRSA and send email alert to infection prevention staff. (Also use other MRSA reduction strategies, e.g., training). | MRSA rates decreased in participating hospitals; data on impact of intervention made available to staff including rapid feedback on progress, etc. Applying strategies to other hospital-acquired infections. | • Reduced and backlogged IT staff and data analysts  
• Competing public health initiatives  
• Communication problems  
• Labs not willing to share data with “research org” |
| **All-Payer Claims Database Council (APCD) program to support states in developing and deploying APCD systems.** National federation of government, private, nonprofit academic orgs. Funding from the Commonwealth Fund, Academy Health’s State Coverage Initiative, AHRQ, National Governor’s Assn, California Healthcare Foundations and others.¹ | Use of state claims data to provide information on costs. Aim to develop seamless, cross-state dataset of longitudinal patient records. | Council coordinates and supports state APCDs, helps to harmonize and develop data collection rules across state databases. Builds consensus for development of APCD data collection standards as foundation for cross-state analytics and reporting. | Current participation by nearly 2 dozen states. Provides multi-state analysis platform. Developing strategy to integrate Medicare data into APCD. | • Lack of federal and state funding  
• Lack of uniform approach to building, funding and supporting APCDs  
• Incomplete data, especially Medicare |
| **Harmonization and Use of a Healthcare Quality Measure for Surgical Site Infections (SSI).** Collaboration between CDC and American College of Surgeons (ASC) to harmonize different SSI measures.³ | Collaboration for harmonization of quality measure data used for SSI surveillance in CDC’s National Healthcare Safety Network and ASC’s National Surgical Quality Improvement Program. | CDC and ACS partnered to improve SSI data supply chain, starting with agreement on one set of SSI measurement specs. Work toward data transfer from ASC web reporting system to CDC’s system. | Harmonized SSI measure endorsed by NQF and adopted by CMS for hospital IQR program in Jan. 2012. Initial harmonization effort provides momentum for related challenges. | • Differences in measure specifications in the areas of procedure sampling  
• Duration of patient follow up and risk adjustment of outcomes |
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<td><strong>Patient characteristics associated with venous thromboembolic events: a cohort study using pooled EHR data.</strong> MetroHealth System (Case Western Reserve Univ). Demonstrate potential of de-identified clinical data from multiple healthcare systems with different EHRs for use in large retrospective studies.⁴</td>
<td>Use of aggregated, standardized, normalized EHR data from different health systems to perform clinical research.</td>
<td>Used pooled, de-identified data from multiple systems with distinct EHRs. Data were standardized and normalized via common ontologies, and searchable via HIPAA-compliant, patient de-identified web app.</td>
<td>Cohort study of EHR data from 1 million patients was much larger, performed with much fewer resources, and much faster than equivalent prospective cohort study.</td>
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<td><strong>BioSense 2.0.</strong> CDC program tracks health problems as they evolve and provides public health officials with data and tools to better prepare and coordinate responses. Mandated in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Administered by ASTHO, Council of State and Territorial Epidemiologists, NACCHO, Int’l Soc for Disease Surveillance.⁵</td>
<td>Use of EHR data for biosurveillance; public health syndromic surveillance messaging for MU. Nationwide integrated system for early detection and assessment of bioterrorism-related illnesses. Cloud-based environment provides situation awareness for all-hazard health-related threats.</td>
<td>Distributed environment, (joint state, local and federal) provides secure data storage space, analytic tools, and shared environment for public health surveillance. Systematically collects large volumes of EHR data from clinical and non-clinical services (ED, inpatient, ambulatory) in near “real time.”</td>
<td>Enables monitoring of numerous health conditions, and rapid sharing of data by state and local health depts. and CDC. Examples of use: BioSense data was used to enhance surveillance for dengue by identifying people with dengue symptoms; to monitor levels of heat-related illness during heat wave.</td>
<td>None noted.</td>
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<td><strong>BioVU.</strong> Vanderbilt Univ. Med. Ctr biorepository, funded by NIH and CTSA; member of NGHRI eMERGE consortium. Collection of patient samples for biorepository using opt-out approach.⁶</td>
<td>Biorepository includes clinical-derived DNA samples linked to de-identified EHRs to support genotype-phenotype research.</td>
<td>Uses patient opt-out model combined with de-identification of corresponding health records and a substantial patient notification program.</td>
<td>As of 9/2012, contained DNA samples from over 150,000 individuals and EHR data from 2 million people who did not opt out. Over 65 papers report results leveraging BioVU. Enables pooling of data and samples from different institutions in biobank. Opt-out rate of 15% over past 5 years.</td>
<td>Uncertainty surrounding implications of adopting opt-out approach. Office of Human Research Protections and DHHS are seeking input on suitability of opt out approach, consideration of public education campaign, etc.</td>
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<td><strong>Mini-Sentinel.</strong> Pilot FDA project to create national surveillance system to monitor safety of FDA-regulated medical products.⁷</td>
<td>Uses EHR data from collaborating institutions to monitor safety; assess changes in use of medical products in response to FDA regulatory actions.</td>
<td>Distributed data network; rapid response feature; transparency; whenever possible aggregate data/de-identified data are used.</td>
<td>Assess links between medical product exposures and health outcomes.</td>
<td>None noted.</td>
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| **Million Veteran Program.** Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC, VA Boston), Harvard Medical School. Sponsored by VA. Enroll 1 million veteran volunteers; obtain blood sample and consent. Program highlights bioethical challenges.⁸ | Biorepository and research program to maximize investment in genomic science by obtaining large sample sizes. | Obtain unified view of all interactions with veterans. Call center for questions; processes heavily automated. Point of Care Clinical Trial: research in the course of care. | Insulin protocol underway, with 83 patients enrolled. | • Bioethical challenges related to patient consent: level of patient consent; how best to obtain consent/when to waive  
• Emergent findings  
• Access to data |
| **NIH Biomedical Translational Research Information System (BTRIS).** NIH intramural resource. Search facility providing intramural researchers with access to clinical research data from many sources, over 36 years. Maximize use of clinical research data to support hypothesis generation and testing. BTRIS data use raises policy issues related to intellectual property and patient privacy.⁹ | BRTIS is a single, unified source for comprehensive data collection for NIH clinical studies. Serves as a means to use clinical data for secondary research and non-research (quality assurance, resource utilization) purposes. De-identified data are contributed from NIH electronic health record systems. | Unified data model to aggregate and organize data from multiple sources; controlled terminology unifying local and standard terminologies. | Has supported dozens of ad hoc queries to identify subjects for study recruitment and data mining. | • Develop policies to address access to active clinical study data  
• Access to data on research subjects collected during and prior to study  
• Notifying subjects about data use  
**Future challenges:**  
• Representation of genetic data to support phenomic/genomic queries  
• Policies to make BTRIS available to extramural investigators  
• Funding to support work on data integration/querying  
• Continued development of data use policies |
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<td><strong>Using EHRs to recruit for clinical trials.</strong> Ohio State Univ. Wexner Medical Center (OSUWMC), Columbia Univ. Medical Center, and Weill Cornell Medical College. NLM-funded. Proposes that an improved longitudinal health record (comprehensive patient clinical summary) can improve screening for clinical trials.</td>
<td>Innovative approach to integrate data in EHRs to generate a longitudinal medical history to accelerate recruitment of patients in trials</td>
<td>“Information fusion,” combines processing of data stored in uncoded, narrative text; extraction of structured data from unstructured data; merging of multiple data sets; and combination of episodic events to create medical portrait.</td>
<td>Project underway for 3 years at OSU. Research efforts focused on extracting/annotating data from OSUWMC EMR; performing studies on medical event coreference resolution; and temporally ordering medical events extracted from clinical narratives. NLM funding will support sharing of data across institutions.</td>
<td>Initial approach is to collaboratively develop research methods, but evaluate research independently without sharing data. In the future, data sharing agreements will be established among the 3 medical centers.</td>
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<td><strong>Integrating Data for Analysis, Anonymization, and Sharing (iDASH).</strong> Project of National Center for Biomedical Computing (NCBC), at the Univ of California, San Diego. Aims to enable data sharing for collaborative scientific discovery and analysis through secure cyberinfrastructure housing data repository with sharing permissions controlled by data contributor, privacy policies that protect and enable data sharing, and analytic tools and web services. Data repository enables developers to integrate heterogeneous data form national biomedical, clinical and informatics communities.</td>
<td>Heterogeneous data from national biomedical, clinical and informatics communities. Protected health information on health conditions includes EHRs and genomic data. Also hosts data sets that do not contain personal health information including physical activity sensor data and de-identified medical images.</td>
<td>Cyberinfrastructure on top of a HIPAA-compliant private cloud; portal to algorithms, open source software, data, and training. Data modeling standards used when possible; maps data to existing component schemas. Data Use Agreement wizard facilitates data sharing. Electronic consent management system embeds education resources.</td>
<td>iDASH platform maturing into secure, privacy-preserving scalable environment for integration and analysis of genomic, transcriptomic, phenotypic, behavioral and environmental data. Reduces burden on data owners and users by allowing outsourcing of data sharing process to specialized team that understands research needs.</td>
<td>Addressing need to balance data privacy and data sharing through privacy policies and processes to regulate data sharing and novel privacy preservation algorithms.</td>
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| **Biomarkers Consortium.** Public/private biomedical research partnership managed by Foundation for NIH. Identifies, develops, funds and executes projects that develop and qualify biomarkers to accelerate development of new drugs and improve care. Founded by FNIH, NIH, FDA, PhRMA and CMS and has 28 other stakeholder members. Aimed at precompetitive research/development combining public health benefit with practical impact on drug development, regulatory decision-making, clinical practice. | Data from biomedical research studies: collect/pool data to power Consortium efforts and disseminate data in findings and/or repositories of samples, and raw data made publicly available. Data comes from literature searches, observational studies and clinical trials. | Data collection enabled by Consortium and FINH's role as trusted 3rd party or 'safe harbor' for collaborative research. Data not stored in centralized infrastructure but remain stored with partners. | 15 launched projects to date, 2 fully completed; 2 in the pipeline. $47 million raised from private sector. 3 major FDA guidances: accelerated approval pathway for breast cancer drugs; new clinical endpoints for therapeutic trials in community-acquired bacterial pneumonia and acute skin infection. 14 journal/book publications. | - Patient confidentiality, informed consent, privacy constraints  
- Need clear research aim that fits precompetitive mission while attracting private sector funding  
- Private sector reluctant to share data: competitive or medico-legal risks  
- Concerns about objectivity of shared data analyses  
- Investigators reluctant to share data due to incentives for research credit/authorship |
<p>| <strong>Tennessee Health Information Exchange Cooperative Agreement Program.</strong> State Office of eHealth and other state agencies working to ensure that providers have affordable, functional options to meet HIE requirements of Meaningful Use. Support patient-centered healthcare; continuous improvements in quality, safety, and efficiency of care; public health. Funded by state, ONC state HIE Cooperative Agreement, CMS. | Help providers adopt Direct Messaging to jumpstart statewide electronic exchange of health information. No data collected/aggregated except to use Direct HIE to submit reportable public health data, e.g., Immunization Registry, Cancer Registry, etc. | Support private sector providers, build awareness of &quot;Direct based&quot; HIE capabilities through extending operations of the Tennessee Regional Extension Center, and pilots. Encourage market-based provision of Direct HIE services to providers | Formulation of plans and strategies is underway. | None noted |</p>
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| **SUPREME-DM DataLink.** Eleven integrated health systems combined de-identified EHR data from nearly 1.1 million people with diabetes in 10 states to create the most comprehensive private sector registry for diabetes in the U.S. Funded by AHRQ. Kaiser Permanente Center for Health Research in the lead. DataLink is part of the Virtual Data Warehouse, a larger data-sharing project by a consortium of 29 healthcare delivery organizations that have agreed to standardize datasets from EHRs to collaborate on research.12 | Inpatient and outpatient health records; lab results, height/weight measurement; pharmacy records. | Ethnically and geographically diverse population of women and men, mirroring the general population with diabetes. A unique resource enabling diabetes comparative effectiveness research, epidemiologic surveillance, and population-based care management studies, and provides useful data source for prevention or treatment clinical trials. | Identified the number of people with diabetes using data contributed from more than 15 million members of 11 health systems. Expanding the DataLink to include members at risk for developing diabetes on the basis of elevated fasting glucose, glucose tolerance, or HbA1c tests that do not meet diagnostic criteria for diabetes, and to identify women with gestational diabetes. | • Inconsistencies in data availability  
• Unrecognized or unmeasurable differences among study sites in EHR use and completeness of data could lead to inaccuracies and potential bias in the estimation of diabetes incidence/prevalence.  
• Patient populations in integrated health delivery systems may not generalize to patients in less integrated settings, in other geographic areas, or to uninsured populations.  
• While a common case identification algorithm was used to identify members with diabetes across all sites, each case was not validated via medical record review. |
<p>| <strong>DARTNnet (Distributed Ambulatory Research in Therapeutics Network).</strong> A federated network of electronic health databases created in 2008 to facilitate quality improvement of primary healthcare and efficiently compile clinically-enriched data for comparative effectiveness research. Nine research networks make up DARTNet Institute offering access to approximately 12.5 million patient visits per year, 5 million patient lives, and approximately five billion data points. Originally funded in 2007 by AHRQ; in 2012, chartered as a 501(c)3 organization. Networks include eNQUIRENet, CoNNECT, CCPC, FREENet, MSAFP RN, SAFTINet, STARNet, UNYNet, and WPRN. 13,14 | Aggregates clinical information from electronic health records, pharmacy utilization databases and billing systems; aggregated information is standardized, de-identified and securely linked via the Web to similar databases in other DARTNet member organizations. | Enables a single query to pull information from multiple databases while maintaining privacy and confidentiality of each database. Designed to support a learning community: prompts clinicians to obtain specific information during a patient encounter; providers learn from best practices of high-performing providers | DARTNet’s capabilities were demonstrated by a retrospective cohort study that evaluated patterns of use, comparative effectiveness and safety of oral diabetes medications for adults with type 2 diabetes. Next steps include expanding technical capabilities, scaling up size and diversity of DARTNet clinical entities and population. | None noted |</p>
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| **Down Syndrome Patient Registry.** National Institute of Child Health and Human Development (NICHD) in partnership with PatientCrossroads announced on Oct. 26, 2012, the creation of a new registry to facilitate contacts and information sharing among families, patients, researchers and parent groups.  
Contact information and health history to be entered by patients or family members into an online, secure, confidential database. Will link researchers seeking volunteers for studies with potential recruits. | Participants can customize their profile, update it, and choose the data they want to display; compare their medical information to that of other registrants both anonymously and confidentially. | New effort | None noted |
<p>| <strong>TransCelerate Biopharma:</strong> 10 major global drug firms establish nonprofit organization to speed drug development by working together in the pre-competitive arena across the global research and development community and sharing research and solutions. Includes Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson &amp; Johnson, Pfizer, Roche’s Genentech, and Sanofi. New group is in response to the critical need to substantially increase number of innovative new medicines while eliminating inefficiencies that drive up R&amp;D costs. | Agreed-upon outcome-oriented objectives and guidelines for sharing data and expertise. | Five clinical trials-related projects initially funded: creation of shared-user interface for investigator site portals; mutual recognition of study-site qualification and training; development of risk-based site monitoring approach and standards; development of clinical data standards; establishment of comparator drug supply model. | New organization | None noted |</p>
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<th>Non-traditional Data Sources</th>
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| **MyBetterFit.** Offers relevant, personalized health information to help users find the right birth control for themselves. Aggregates comments from health forums and parses out relevant information about treatments and side effects to create patient profiles against which users can compare their experiences. | Comments from online health forums on individuals’ experiences with birth control. | Leverages social data and natural language processing to help women learn what works best for them with regard to birth control options. Project goal: Women answer a few questions about their current experiences with birth control and ultimately, their medical history and receive social-data-driven recommendations. | Site is in progress of being built out. As of Oct. 2012, MYBetterFit has analyzed 100,000 comments from 2 forums and has observed that for each drug there are about half a dozen cohorts of patients who respond similarly. Plans include expansion to patients taking drugs for other conditions (e.g., psoriasis, depression, ADHD, menopause). | • my.betterfit.com  
• Article in GIGAOM, Oct. 12, 2012 |
| **dwellSense.** Embeds sensors in homes of adults who live alone and may be at risk of developing dementia or experiencing physical decline that manifests in subtle changes in everyday activities that are hard to identify. Carnegie Mellon University team funded through Project Health Design, a Robert Wood Johnson Foundation program. | Data from in-home sensors that monitor routine tasks (e.g., taking medications, making phone calls, preparing coffee); data useful to help providers and participants to assess long-term cognitive and functional assessment. | Project required convincing participants to allow team to speak to their providers and sign a release form authorizing providers to talk to the team; team needed to engage participants’ busy physicians in reviewing sensor results. | Lesson learned re data issues: information flows among patients, providers, 3rd party services respecting confidentiality and allowing patient control of disclosed data should be key to designing system to share and use patient-generated data about observations of daily living (ODLs) and ADLs. | Project Health Design<sup>18,19</sup> |
| **Health Insights in Real-Time.** An App in the Health Data Initiative Forum, 2012 Health Datapalooza, 3<sup>rd</sup> place in Apps Demos for Community. (Artificial Intelligence Lab, University of Rochester). Use artificial intelligence, natural language processing and machine language to empower providers and policy makers to better understand illnesses as they develop. | Identify illness using Twitter. Tweets are an open data set, providing GPS and timestamps; platform removes bias because people have no incentive to lie—tweets are just a consciousness stream. Although may not always be able to say definitively that individuals who say they are sick, really are sick. | In New York City: display real-time heat map of tweets as snapshot showing sickness developing. Overlay with other data sets (e.g., EPA-designated pollutants, traffic congestion) to see how these data interact with the heat map. Identify social networks and empower individuals to see health status of people in their network. | Example of use of app: identify high density of sick individuals in social network who got sick at the same time to identify disease outbreak. Found a 2010 cluster (high density of sick people) by looking at historical tweets and found that all of them went to a restaurant 3 days before. It took the media 4 months to identify that restaurant as source of salmonella outbreak. | Health Data Initiative Forum: Health Datapalooza<sup>20</sup> |
Non-traditional Data Sources | Purpose/Type of Data | Project Features | Results | Source
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Mobile phone “hot spots.” Analysis of mobile phone data in Kenya to understand human movements (an important component of malaria transmission) to help develop effective national malaria control program. | Mobile phone data compared to malaria risk map | Researchers analyzed mobile phone call data from travel patterns of 15 million Kenyan phone owners over a year. Combined this data with a detailed malaria risk map to estimate malaria parasite movements across the country that could be caused by human movement. | Data from the study enabled analysis of parasite sources and links between hundreds of local settlements. Estimates compared with hospital data from Nairobi show local pockets of transmission likely occurring around edges of Nairobi, contrary to accepted idea that transmission does not occur in the capital. | Wesolowski et al. Science, Oct. 12, 2012

1 [http://omop.fnih.org/](http://omop.fnih.org/)
2 [http://www.apcouncil.org/](http://www.apcouncil.org/)
6 [http://vanderbilt.edu/oor/cores/biovu-vanderbilt-dna-databank/](http://vanderbilt.edu/oor/cores/biovu-vanderbilt-dna-databank/)
7 [http://mini-sentinel.org/](http://mini-sentinel.org/)
10 [http://idash.ucsd.edu/](http://idash.ucsd.edu/)
Examples of Government Agency/Organization Data Use Programs and Policies

This matrix highlights examples of federal government agency and organizational activities related to health data use and sharing. The entries include reports on data privacy issues; information on relevant regulations; descriptions of tools/systems to provide access to research, clinical and public health data; and outlines of programs funded to explore various data use challenges and opportunities. Information was gathered from agency/organization web sources.

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| **Agency for Healthcare Research and Quality (AHRQ)** | • AHRQ manages funds designated by ARRA to build the infrastructure for conducting CER with electronic clinical data, including EHRs.  
• As part of this initiative, AHRQ has funded 12 research projects through 3 programs: the Prospective Outcome Systems using Patient-specific Electronic Data to Compare Tests and Therapies (PROSPECT) studies; Enhanced Registries for Quality Improvement (QI) and CER; and Scalable Distributed Research Networks (DRN) for CER. See [http://higherlogicedownload.s3.amazonaws.com/EDMFORUMRESEARCHPORTAL/ebb29509-0ee1-4015-acc2-2ee4c7642828/UploadedFiles/edmprojectprofiles081412.pdf](http://higherlogicedownload.s3.amazonaws.com/EDMFORUMRESEARCHPORTAL/ebb29509-0ee1-4015-acc2-2ee4c7642828/UploadedFiles/edmprojectprofiles081412.pdf)  
• Electronic Data Methods Forum for CER is an additional project funded by AHRQ to serve as a harmonizing entity for the research projects noted above, engaging key stakeholders and facilitating synthesis and dissemination of lessons learned. See [http://www.edm-forum.org/publicgrant/Home/](http://www.edm-forum.org/publicgrant/Home/) |
<p>| <strong>Centers for Disease Control and Prevention (CDC)</strong> | • BioSense 2.0 provides timely insight into the health of communities, regions, and the nation by offering a variety of features to improve data collection, standardization, storage, analysis, and collaboration. Using the latest technology, BioSense 2.0 integrates current health data shared by health departments from a variety of sources to provide insight on the health of communities and the country. BioSense 2.0 is redesign of the BioSense project to provide nationwide and regional situational awareness for all-hazard health-related threats (beyond bioterrorism) and to support national, state, and local responses to those threats. See <a href="http://www.cdc.gov/biosense/">http://www.cdc.gov/biosense/</a> |</p>
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• The Medicare EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) that demonstrate meaningful use of certified EHR technology. The Medicaid EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and CAHs as they adopt, implement, upgrade, or demonstrate meaningful use of certified EHR technology in their first year of participation and demonstrate meaningful use for up to five remaining participation years. See [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html)  
• Medicare makes limited (de-identified) datasets (LDS) available. To qualify for LDS, data requesters must show that their proposed use of the data meets the disclosure provisions for research purposes as defined in both the HIPAA and the Privacy Act. The research purpose must relate to projects that could ultimately improve the care provided to Medicare patients and policies that govern the care. This includes projects related to improving the quality of life for Medicare beneficiaries or improving the administration of the Medicare program, including payment related projects and the creation of analytical reports. See [http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html)  
• CMS Innovation Center awarded Health Care Innovation grants in 2012 to organizations to implement projects in communities across the nation that aim to deliver better health, improved care and lower costs to people enrolled in Medicare, Medicaid and the Children’s Health Insurance Program (CHIP), particularly those with the highest healthcare needs. Several of these awardees are exploring EHR data exchange/sharing innovations. See [http://innovations.cms.gov/initiatives/Innovation-Awards/index.html](http://innovations.cms.gov/initiatives/Innovation-Awards/index.html) |
• VA and the Department of Defense (DoD) began working together in 2002 to share health information between their two Electronic Health Records (EHR). VA’s EHR is VistA CPRS* and DoD’s is AHLTA. Transferring information between VistA CPRS and AHLTA was a major undertaking, since both EHR’s were created using different types of software application. [http://www.ehealth.va.gov/vadod/](http://www.ehealth.va.gov/vadod/) |
<p>| <strong>Department of Homeland Security (DHS)</strong> | • In 2012, DHS awarded a $3 million contract to use social media analytics to enhance the biosurveillance capabilities of the Office of Health Affairs (OHA), and to improve data sharing and collaboration between OHA and its partners. The social media analytics pilot will manage, link, and analyze data from social media networks in real time to better inform and protect the public in case of a national health emergency such as an infectious disease outbreak or a biological attack. See <a href="http://newsroom.accenture.com/news/accenture-awarded-biosurveillance-contract-from-department-of-homeland-security.htm">http://newsroom.accenture.com/news/accenture-awarded-biosurveillance-contract-from-department-of-homeland-security.htm</a> |</p>
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<td>Food and Drug Administration (FDA)</td>
<td>• Mini-Sentinel is a pilot FDA project to create the Sentinel System to monitor the safety of FDA-regulated medical products. Mini-Sentinel uses pre-existing electronic healthcare data from multiple sources. Collaborating institutions provide access to data as well as scientific and organizational expertise. See <a href="http://mini-sentinel.org/">http://mini-sentinel.org/</a></td>
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<td>Coordinating Council for Comparative Effectiveness Research</td>
<td>• Federal Coordinating Council for Comparative Effectiveness Research, (created by ARRA to foster optimum coordination of CER conducted or supported by Federal departments and agencies) issued a 2009 report to the President and the Congress. The Federal Coordinating Council was ended by the Affordable Care Act. See <a href="http://www.hhs.gov/recovery/programs/cer/">http://www.hhs.gov/recovery/programs/cer/</a></td>
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| Institute of Medicine (IOM)            | • IOM: *Sharing Clinical Research Data: A Workshop*. Pharmaceutical companies, academics, and government agencies such as the Food and Drug Administration and the National Institutes of Health have large quantities of clinical research data. Data sharing within each sector and across sectors could facilitate scientific and public health advances and could enhance analysis of safety and efficacy. Much of this information, however, is never published. This workshop will explore barriers to sharing of clinical research data, specifically clinical trial data, and strategies for enhancing sharing within sectors and among sectors to facilitate research and development of effective, safe, and needed products. [http://www.iom.edu/Activities/Research/SharingClinicalResearchData/2012-OCT-04.aspx](http://www.iom.edu/Activities/Research/SharingClinicalResearchData/2012-OCT-04.aspx)  
• IOM: *Digital Data Improvement Priorities for Continuous Learning in Health and Health Care - Workshop Summary*. Digital health data are the lifeblood of a continuous learning health system. A steady flow of reliable data is necessary to coordinate and monitor patient care, analyze and improve systems of care, conduct research to develop new products and approaches, assess the effectiveness of medical interventions, and advance population health. The totality of available health data is a crucial resource that should be considered an invaluable public asset in the pursuit of better care, improved health, and lower health care costs. [http://www.iom.edu/Reports/2012/Digital-Data-Improvement-Priorities-for-Continuous-Learning-in-Health-and-Health-Care.aspx](http://www.iom.edu/Reports/2012/Digital-Data-Improvement-Priorities-for-Continuous-Learning-in-Health-and-Health-Care.aspx)  
• IOM: Communicating with Patients on Health Care Evidence, released September 2012, accessible at [Research was conducted in three phases (environmental scan, qualitative research/focus groups and quantitative/survey analysis) to determine strategies to raise awareness of and increase demand for medical evidence among patients, providers, healthcare organizations and policy makers.](http://www.iom.edu/Global/Perspectives/2012/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf) |
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| **National Committee on Vital and Health Statistics (NCVHS)** | • Submitted a 2011 report to DHHS: *The Community as a Learning System: Using Local Data to Improve Local Health*. Discusses the need to build trust to support data use through technological mechanisms, data stewardship, community education and engagement, transparency, and governance. See [http://www.ncvhs.hhs.gov/111213chip.pdf](http://www.ncvhs.hhs.gov/111213chip.pdf)  
| **National Science Foundation (NSF)** | • NSF Data Sharing Policy: Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing. See Award & Administration Guide (AAG) Chapter VI.D.4. [http://www.nsf.gov/bfa/dias/policy/dmp.jsp](http://www.nsf.gov/bfa/dias/policy/dmp.jsp) |
| **National Institutes of Health (NIH)** | • NIH Biomedical Translational Research Information System (BTRIS) is a search facility providing intramural researchers with access to clinical research data from many sources over 36 years. It maximizes use of clinical research data to support hypothesis generation and testing. See [http://btris.nih.gov/](http://btris.nih.gov/)  
• Clinical Translational and Science Awards (CTSA) program is comprised of about 60 academic medical institutions and a coordinating center working together to accelerate the translation of laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train clinical and translational researchers. Examples of activities relevant to data sharing include cataloging of detailed information on EHR data availability among consortium members; maintenance of 28 biobanks in which biological samples are linked to clinical data derived from a continuously updated electronic system (e.g. an EHR); and use of cTAKES (Clinical Text Analytics and Knowledge Extraction System), an open source, natural language processing system for information extraction from EHR free text. See [https://www.ctsacentral.org/](https://www.ctsacentral.org/)  
• Nearly 100 NIH intramural investigators have accessed the Database of Genotypes and Phenotypes (dbGaP) (a central repository of genome-wide association studies data) to conduct secondary studies on genetic risk factors associated with the major mood disorders, schizophrenia, asthma, and autism; insights into a key metabolic pathway and neurodegenerative diseases; and improved statistical methods to study X-linked diseases such as age-related macular degeneration. See [http://irp.nih.gov/catalyst/v20i3/news-you-can-use](http://irp.nih.gov/catalyst/v20i3/news-you-can-use)  
• Other data sharing documents: [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_resources.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_resources.htm) |
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<td>Office of the National Coordinator for Health Information</td>
<td>• Health IT Policy Committee made recommendations on secondary use privacy issues (10/18/2011). Discusses what secondary uses of data constitute “research” and what is needed to build and maintain trust in secondary data uses. See <a href="http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__policy_recommendations/1815">http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__policy_recommendations/1815</a></td>
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<td>Technology (ONC)</td>
<td>• Created the Investing in Innovation (i2) program (2011) to host competitions to develop tools or programs that support HIT innovation including a focus on secure sharing of health information. See <a href="http://www.hhs.gov/news/press/2011pres/06/20110608a.html">http://www.hhs.gov/news/press/2011pres/06/20110608a.html</a></td>
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<td>• Funded the Strategic Health IT Advanced Research Projects (SHARP) to confront challenges to adoption of EHRs and other forms of health IT. Grants focus on secondary use of EHR information, security and health IT, patient-centered decision-making support, and health care application and network design. See <a href="http://www.healthit.gov/policy-researchers-implementers/strategic-health-it-advanced-research-projects-sharp">http://www.healthit.gov/policy-researchers-implementers/strategic-health-it-advanced-research-projects-sharp</a></td>
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<td>• Issued 2008 report, Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information, which discussed a framework for data security and privacy principles and policies. See <a href="http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf">http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf</a></td>
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<td>President’s Council of Advisors on Science and Technology</td>
<td>• 2010 Report by the President’s Council of Advisors on Science and Technology: Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward. Report discusses improved access to patient data including privacy and security considerations. See <a href="http://www.whitehouse.gov/sites/default/files/pdf/fact-sheets/beacon-communities-lessons-learned.pdf">http://www.whitehouse.gov/sites/default/files/pdf/fact-sheets/beacon-communities-lessons-learned.pdf</a></td>
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<td>(PCAST)</td>
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<td>• The Patient-Centered Outcomes Research Institute (PCORI) is authorized by Congress to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI’s research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options. PCORI is developing research methods that support the engagement and meaningful inclusion of patients at every step of the research process. See <a href="http://www.pcori.org/">http://www.pcori.org/</a></td>
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<td>Institute (PCORI)</td>
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<td>Social Security</td>
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<td>Administration (SSA)</td>
<td>• In 2011, the Social Security Administration limited access to state records that are part of the Social Security Death Master File. Without an easily accessed, updated national death index, it will be harder for researchers to obtain mortality data. See <a href="http://www.nytimes.com/2012/10/09/us/social-security-death-record-limits-hinder-researchers.html?_r=0&amp;pagewanted=print">http://www.nytimes.com/2012/10/09/us/social-security-death-record-limits-hinder-researchers.html?_r=0&amp;pagewanted=print</a></td>
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<td>Veterans Health Affairs (VHA) (see also DoD)</td>
<td>• My HealtheVet is the VA’s Personal Health Record. It was designed for veterans, active duty Service members, their dependents and caregivers. My HealtheVet helps individuals partner with their health care team. <a href="https://www.myhealth.va.gov/index.html">https://www.myhealth.va.gov/index.html</a></td>
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