AMIA 2008 Health Policy Conference  
September 15, 2008

Meeting Goals and Objectives

- Identify the most relevant ethical, political, technical, technological and social factors and challenges to creating, translating, disseminating and integrating evidence into clinical care and practice.
- Explore the role of informatics in accelerating the creation, collection, translation, dissemination and adoption of clinical research into knowledge, evidence, and practice.
- Develop a potential framework for collaboration.
- Create a short range action plan (2-3 years) that could be pursued by the participants and other stakeholders in order to fulfill the detected needs.

Meeting Attributes and Format

The meeting has been designed to encourage a high degree of participant interactivity. We anticipate lively discussions with identification of white elephants, logjams, jugernaucsts as well as areas of disagreement. Discussions are oriented toward identifying potential policy-oriented solutions. During the meeting there will be a general large group opening session, facilitated small-group breakout discussions based on scenarios, and plenary sessions to summarize results and formulate recommendations. During the small groups, participants will be asked to identify a note taker and a spokesperson to record and then share the group’s findings when we reconvene into the larger general session. Following the meeting, a summary report with policy recommendations will be created.

Meeting Steering Committee

- Doug Fridsma, co-chair, Arizona State University
- Suzanne Markel-Fox, co-chair, GSK
- David Bates, AMIA Chair, Partners Healthcare
- Meryl Bloomrosen, AMIA
- Don Detmer, AMIA
- Srinid Kalluri, PercipEnz Technologies, Inc.
- Kraig Kinchen, Lilly
- David Leventhal, Pfizer
- Joyce Niland, City of Hope Cancer Center
- Phil Payne, Ohio State University
- Mark Weiner, University of Penn
Assuming an increasingly evidenced-based, patient-centered, consumer-connected health delivery and learning system:

- What are the ethical, political, technical, technological, and social factors and challenges that will impact the formulation of national policy and the role of informatics in this future?
- What are the most likely strategies to enhance dissemination, diffusion, and adoption of evidence-based care? For non-academic environments? For safety net providers and their patients? For special populations?

1. Identifying and Evaluating Practice Patterns
A new medication for Type 2 diabetes has been developed and a health plan would like to compare the effectiveness and safety of this therapy with an existing therapy in its member population. Most of their primary care physicians have electronic medical records, but there is no health plan-wide medical record. The health plan would like to assess clinical presentation, drug utilization, emergency room and hospital admissions, and laboratory assessments of patients with Type 2 diabetes. If the new medication is more effective than the existing therapy, the health plan would like to use that evidence to support recommendations within their own patient network, and publish the results more broadly. The health plan has recently launched a remote eHealth consultation service and wishes to provide this service electronically to patients who subscribe to it. Patients will be expected to provide data on their use of the drug through the consultation service.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- What are the opportunities to drive integration of clinical data and EHR PHR systems with research?
- What are the key requirements to accelerating the use of EHR PHR systems as reliable evidence sources?
- What are the key strategic pathways in moving from the current approaches to real-time evidence generation using EHR PHR systems?
2. Identifying Patients to Participate in Research
An academic organization has developed a new intervention for Type 2 diabetes and has developed a clinical trial protocol to test this new intervention. An electronic health record (EHR) is available at the institution with encoded data regarding all of their current patients. Patients who have been seen recently have signed a consent form indicating they are willing to be contacted for experimental treatment should an applicable trial be available, while patients who have not been seen recently have not been approached for such consent. The organization would like to use the electronic health record to identify patients who could benefit from this new intervention and participate in the clinical trial.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- If we believe that electronic healthcare data has utility for identifying potential clinical trial participants, what are the relevant policy-related issues and what are promising approaches for dealing with these issues?
- What are the policy implications and considerations?
- What are the implications of other entities (RHIOs, payers, etc.) considering opportunities to link patients to clinical trials?

3. Collecting Data for Mining and Analytics
“Shopping” is a new jargon for combining, summarizing, and aggregating data (often of different types and formats) with many different companies providing these services in both medical and nonmedical domains. A researcher in an academic healthcare center would like to aggregate clinical, genomic, public health and demographic data drawn from a variety of different resources to provide a "snapshot" of the health of the community. Using sophisticated data mining techniques, he would like to identify areas in which targeted intervention could have the most value in improving the health of the population. Not only do the data described in the scenario come from different sources, they reflect different patients. There is no direct link between the patients for whom clinical data are available and for whom genomic data are available.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- How will new, disparate, and combined sources of data, such as personal health records, genetic data, and data from implantable and medical devices contribute to evidence-based practice, shared knowledge, and shared decision making?
4. Accessing Research Protocols and Treatment

A patient has recently been diagnosed with a progressive, debilitating disease. The patient contacts her primary care provider to see if there are any clinical trials or other research studies for which she may be eligible. While a few clinical trials were identified, participation in them would mean a 2 1/2 hour drive to a tertiary academic medical center. The patient asks if she can participate in one of these trials but receive the treatments and evaluation associated with them in her primary care physician’s office. If these options, identified by the primary care provider don’t work out, she is thinking about checking on Internet support groups or patient-initiated disease networks which could provide her access to information about other cutting-edge research and treatment options.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- How is technology altering the roles and responsibilities of consumers with respect to identifying treatment options, including experimental treatments?
- What are the implications of these changes for clinical trial recruitment?
5. Turning Evidence into Practice
A panel of experts has been convened to assess current screening practices for a particular kind of cancer. The discussions are somewhat contentious as to what the best practice should be and thus, a series of consensus guidelines are written that each member of the committee might be able to agree to. Although the guidelines reflect “best practice,” they are written in a way that allows for some interpretation by a practicing physician, and include the variety of perspectives from each of the experts. Since this particular recommendation is tied to performance pay for the physician, the technical staff at the local hospital has been asked to implement these guidelines in a computer-based algorithm. The technical experts encounter huge difficulties when translating the guideline into a consistent set of rules to support best practice.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- How can new and combined sources of data (such as EHRs, genetic data, implantable and medical devices) contribute to evidence-based practice, shared knowledge, shared decision-making?
- What cooperative/collaborative work among stakeholders can best accelerate the uptake and adoption of knowledge, evidence, care, and practice?
- How can EHR data be used to help guide the creation of a guideline that provides a clinically significant threshold enabling meaningful discrimination between good and poor performing providers?
- What policies does an institution need to determine the appropriate process for implementing clinical decision support algorithms?

6. Using New and Combined Sources of Data
A patient has recently enrolled in a personal health record (PHR) website hosted by a for-profit organization. Her PHR allows her to collect information from a variety of healthcare providers, laboratory, and educational resources into one place. It also allows her to designate access to specific portions of her record to specific providers. The hosting organization promises that this record will eventually be able to automatically obtain laboratory, pharmacy, and clinical data from various sources. The hosting organization has
set up this website and has a data use agreement with all participants that allows the organization to reuse information in the PHR for any purpose as long as it is de-identified. In addition, the patient participates in a home-based diabetes monitoring program and wonders how this data can be used.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- How might the role of patient-centered health information technology (PCHIT) such as personal medical devices and services affect clinical research, evidence and care? What are the relevant issues and concepts (such as transparency and stewardship) relating to consumer awareness of their role and participation in helping society to advance science and the creation of evidence and how do we advance public awareness?

7. Reporting Adverse Events

Data and safety monitoring of clinical studies is mandated to maximize patient safety throughout the research process and to ensure that the research remains scientifically and ethically sound. Timely and accurate reporting of Adverse Events (AE) is critical to the safety of clinical trials research. Manual capture and evaluation of this information poses many challenges. There may be up to 50 possible AE categories per patient, with multiple assessments per unit time for dozens of patients per trial and hundreds of open trials. AE criteria are not organized for efficient and effective traversal by clinicians and staff. Post-marketing surveillance could by very valuable in detecting previously unsuspected untoward events. Physicians at an academic research center would like to utilize electronic medical record data to automatically monitor and assess possible adverse events in a Phase IV clinical trial in near real time.

- What are the key challenges depicted within this scenario? How might the evolution of new and combined evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- What are the most promising approaches for building EHRs to enhance the prospects of real-time research capacity as well as their overall utility for research and how can these approaches be encouraged?
- What are the policy considerations in working to ensure that EHRs are designed to advance their utility for research?

A marketing salesperson has recently been seen in an urgent care center for a cough and upper respiratory illness before a series of business trips that will carry him across the country and to an international sales conference. By the time that his tests and culture results were available, he had left the clinic and begun his trip. The tests and culture results indicate that the salesperson has a serious, contagious respiratory illness that would trigger the public health system. Although the clinic has his medical record number, his primary care provider information, and other information, they need to act quickly to protect both the patient (and begin treatment) and protect the public who may be at risk of being infected with this contagious respiratory disease. The urgent care clinic would like to rapidly notify the patient, and activate the public health care system to protect the patient and the public.

- What are the key challenges depicted within this scenario? How might the evolution of new evidence sources help mitigate challenges and facilitate proposed solutions?
- What are the policy implications and considerations?
- How will new and combined sources of data contribute to evidence-based practice and rapid response to serious public health concerns?
- What are promising approaches to dealing with policy-related issues raised by use of personal health data for public health purposes?
- How can we enhance efforts to improve the collection, analysis, communication, and utilization of global health data in an evidenced-based system and for global health decision making?