An Information Policy Framework for Evidence-based Knowledge and Practice

September 15, 2008

Reston VA
Welcome and Opening Remarks

David W. Bates, MD
-Chair, AMIA Board of Directors
American Medical Informatics Association

The professional home of biomedical and health informatics
AMIA’s Vision: Home for AMIAble Informaticians

- Through informatics, transform health & health care for individuals & populations
  - Care that is Equitable, Efficient, Effective, Patient-centered, Timely, Safe
- Transform informatics from a serious avocation to a formally recognized health profession
AMIA’s Domains

- Applied clinical informatics (including health care and personal health management)
- Clinical research informatics (including clinical trials, clinical research and those methods used in translational bioinformatics)
- Public health/population informatics
- Translational bioinformatics (the research itself)
Selected AMIA Milestones

- **Clinical Informatics**
  - RWJF grant for clinical informatics as a medical specialty
  - Signature 10 x 10 Programs
- **Clinical Research Informatics**
  - CRIS Task Force; 10x10 Course on Research Informatics - U Cinn.
- **Translational Bioinformatics**
  - First Annual Summit on Translational Bioinformatics - March ‘08
  - Stanford 10x10 course on bioinformatics
- **Public Health Informatics**
  - CDC cooperative agreement to advance public health informatics training
- **Global Informatics**
  - Rockefeller project support grant for eHealth Capacity Building & informatics training plan development
Upcoming AMIA Events

AMIA 2008 Annual Symposium
Hilton Washington Hotel and Towers
Washington, DC
November 8-12, 2008

2nd Annual Summit on Translational Bioinformatics
Grand Hyatt San Francisco
San Francisco, California
March 15-17, 2009

2009 AMIA Spring Congress
Walt Disney World Swan
Orlando, Florida
May 28-30, 2009

Jaap Suermondt,
Program Chair

Yves Lussier,
Program Chair

Patti Abbott,
Program Chair
Overview of Policy and Legislative Environmental Happenings

- Doug Peddicord, Washington Health Advocates
Discussion Topics

- Brief Presidential Candidates Overview
- Selected Legislative Overview
- Selected Administrative and Agency Overview
Presidential Candidate Overview

- Comparative Effectiveness
  - Presidential Candidates - Obama and McCain
    - Both include comparative effectiveness in their health proposals as a way of reining in costs while improving quality
    - Both want to establish an independent institute for review and research
      - Few other details from both sides
Presidential Candidate Overview con’t

• Health Information Technology
  - Sen. Barack Obama
    • Obama will invest $10 billion a year over the next five years to move the U.S. health care system to broad adoption of standards-based electronic health information systems, including electronic health records, and will phase in requirements for full implementation of health IT
  - Sen. John McCain
    • McCain supports the adoption of health information technology, but offers little insight to his actual plans
Presidential Candidate Overview con’t

- The Information Technology Association of America (ITAA) gave both Obama and McCain the grades of “incomplete” on their overall focus on and vision for technology-driven innovation.
Legislative Overview

• Possible Legislation in 2009
  - “Comparative Effectiveness Research Act of 2008” (S. 3408)
    • Introduced by Sen. Baucus (D-MT) - Chairman of the Committee on Finance
    • “Doctors and patients need reliable, unbiased information about the effectiveness of treatments to determine the best care possible, but right now that data is scarce and unorganized.” - Sen. Baucus
Legislative Overview con’t

- “Comparative Effectiveness Research Act of 2008”
  - Establishes a private, non profit, organization called the Health Care Comparative Effectiveness Research Institute
    - Will create a Methodology Committee to develop standards for the Institute’s research
    - Transparency and public input are key components of the Institute’s research
    - Much of the research will be performed by NIH and AHRQ
AHIC and ONC

• Clinical research was originally identified as a priority by AHIC but was not selected for use case development.

• June 2008 meeting: AHIC recommended that ONC explore options for a ‘supplemental’ process to support use case development, standards harmonization and consideration in the rest of the national HIT agenda activities.

• July 2008 Panel Discussion on Clinical Research and Electronic Health Information
AHRQ

  - Provides a beta version of standardized guidelines for health care agencies to voluntarily report patient safety and health care information. Empowered by the Patient Safety and Quality Improvement Act of 2005, AHRQ-funded Patient Safety Organizations will analyze and organize the data
- Evidence-based Practice Centers
  - In 1997, AHRQ launched its initiative to promote evidence-based practice and established 12 Evidence-based Practice Centers (EPCs)
- Centers for Education and Research on Therapeutics (CERTs)
  - A research program administered by AHRQ in consultation with the FDA
  - To conduct research and provide education that will advance the optimal use of drugs, medical devices, and biological products
  - Develop as a result of specific direction provided by Congress in the 1997 Food and Drug Administration Modernization Act
CMS

  - HHS adopts X12 Version 5010 and NCPDP Version D.0 for the HIPAA transactions. Proposes to adopt a new standard for Medicaid subrogation, for pharmacy claims, known as NCPDP Version 3.0.
  - HHS proposes to adopt the ICD-10 code set to replace the ICD-9 code sets in HIPAA transactions. These two rules apply to HIPAA covered entities, including health plans, health care clearinghouses, and certain health care providers.

- Medicare Improvements for Patients and Providers Act of 2008
  - Enacted in July, Medicare will pay more to physicians that e-prescribe and less to those who don't.
  - The law calls for incentive payments for e-prescribing of 2% in 2009 and 2010, 1% in 2011 and 2012, and 0.5% in 2013.
  - Beginning in 2012, Medicare payments to physicians not electronically prescribing would be reduced by 1%, then 1.5% in 2013 and 2% in subsequent years.
  - The legislation also requires reporting of any e-prescribing quality measures established under Medicare's physician reporting system.
FDA

- Food and Drug Administration Amendments Act of 2007 (FDAAA)
  - Section 905, The Secretary shall, not later than 2 years after the date of the enactment … in collaboration with public, academic, and private entities, develop methods to obtain access to disparate data sources … develop validated methods for the establishment of a post market risk identification and analysis system to link and analyze safety data from multiple sources

- Critical Path Initiative
  - Stimulate and facilitate a national effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or “proof of concept” into a medical product

- Sentinel Initiative (report issued May 2008)
  - Created in response to the Food and Drug Administration Amendments Act (FDAAA)
  - The network will foster the electronic flow of medical product safety information from electronic databases and surveillance reporting systems, through risk identification and analysis processes, to healthcare practitioners and patients at point-of-care, while protecting patient privacy
NCVHS

• July 17, 2008 - 23 Building Blocks for Quality: The View from 2008
• April 24, 2008 - Enhancing Protections for Uses of Health Data: A Stewardship Framework
• Report to the Secretary: January 28, 2008 - - Quality Measurement and Public Reporting in the Current Health Care Environment
NIH Clinical and Translational Science Award (CTSA) Program

• National Center for Research Resources (NCRR)
  - Clinical Translational Science Awards (CTSAs)
    • 38 academic health centers in 23 states
    • CTSA Informatics Steering Committee focused on interoperability and privacy issues
      - Chaired by AMIA member Bill Hersh - Oregon Health & Science University
    • FDA funding may prevent the NCRR from achieving their goal of 60 CTSAs
NIH Genome-wide Association Studies

• To identify common genetic factors that influence health and disease. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.

• A paper published in *PLoS Genetics* described a statistical method for resolving individual genotypes within a mix of DNA samples or data sets containing aggregate single-nucleotide polymorphism data.

• September 2008 NIH removed aggregate genomic data from the NIH publicly available Websites.
Thoughts on Evidence and Knowledge in a Connected World

Don E. Detmer, MD, MA
- President/CEO, AMIA
Meeting Sponsors

APA

GlaxoSmithKline

IMO®

Lilly

PercipEnz

Innovating through Collaboration

Pfizer

AMIA
Government Leadership Present

- AHRQ
- CDC
- CMS
- DoD
- FDA
- HRSA
- NIH
- ONC
- TATRC
- VA
- (IOM)
2008 AMIA Health Policy 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
- Srini 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 Pennsylvania
AMIA’s 2006 & 2007 Health Policy Meetings


• AHIC and NCVHS Testimony
Goals & Objectives

Premise:
Healthcare in a ‘wired’ world must collate & use evidence-based knowledge in a timely & coherent fashion. Informatics is key to achieving this objective. How do we make it happen?

Tasks for Today:
- Review Key Challenges (ethical, political, technical, technological &/or social) to the creation, translation, & dissemination of evidence-based knowledge into clinical use in a timely fashion.
- Identify Roles for Informatics
- Develop a Framework to support the transformation
- Create an Action Plan (2-3 years) to begin to address the objectives
IOM Roundtable on Evidence-based Medicine

- Develop a learning healthcare system designed to generate & apply the best evidence for the collaborative health care choices of each patient & provider;
- Drive the process of discovery as a natural outgrowth of patient care;
- Ensure innovation, quality, safety, & value in health care.
Robust Knowledge Generation

- **Premise:** Improved efficiency & effectiveness of care depends on the best knowledge in a clear format for use by health professionals & patients when making decisions.

- This encompasses a set of complex processes;
  - basic, translational, & clinical research
  - collecting patient data on care & outcomes & making it available to researchers & clinicians
  - organizing knowledge needed for decisions
  - Delivery mechanisms for dissemination & adoption
  - Continually evaluating care & outcomes to create better applications

From Data to Knowledge to Evidence to Outcomes

Multiple & Diverse Data Sources

DATA
- Longitudinal
- Real-time
- Demographic
- Clinical
- Financial

TRUSTED, EVIDENCE-BASE
New Knowledge, Tools, Applications, Treatments, Devices, Interventions, Therapies, Medications ……

Providers
Researchers
Payors
Academicians

Patients, Caregivers, Consumers & Communities

Policy Makers & Regulators

Industry (HIT vendors, pharmaceutical companies, device manufacturers; publishers)

Awareness, Acceptance, Adoption, Assessment

Adapted from Joe Volpe -- J&J
Overarching Questions

• What does the future evidence-based care & delivery system look like in a connected world?

• What are the most likely strategies to enhance dissemination, diffusion, & adoption of knowledge & evidence-based care & practice?
  - For non-academic environments?
  - For safety net providers and their patients?
  - For special populations?

• How can informatics accelerate use of clinical data for new insights/knowledge, research, evidence & care?
Overarching Questions (cont)

- How will new & combined sources of data (personal health records, genetic data, implantable & medical devices) contribute to evidence-based practice, shared knowledge, & shared decision-making?
- What policy changes or initiatives are necessary to accelerate the evolution of new & combined evidence sources?
- What actions from public sector agencies & private sector organizations would most enhance & accelerate the uptake & adoption of knowledge, evidence, care, & practice?
“If the living, experiencing being is an intimate participant in the activities of the world to which it belongs, then knowledge is a mode of participation, valuable in the degree in which it is effective. It cannot be the view of an unconcerned spectator.”

- J. Dewey, 1926 (1916)  
  Democracy & Education
Some Disruptive Technologies:
 Telegraph, Telephone, Television, Internet - Web 1.0 & Web 2.0

“If you study politics, military events & things like that, you’re studying how history gets made from the top down.

But you can also study the common people, history from the bottom up, because they’re making history, as well.”

- Daniel Walker Howe
Web 1.0 v. Web 2.0

- Web 1.0 is a disruptive technology.
  - The Internet changes everything. Bill Gates.

- Web 2.0 is yet again another disruptive technology.
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<td>• Top down</td>
<td>• Bottom up</td>
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<td>• “Controlled from on high”</td>
<td>• “Power to the People”</td>
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<td>• Privacy #1</td>
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In the News

- **Protecting Aggregate Genomic Data**
  - In response to a recently reported statistical method for resolving individual genotypes within a mix of DNA samples or data sets containing aggregate single-nucleotide polymorphism data, NIH is taking action to protect the individuals who have contributed to its databases by removing aggregated data from open-access databases. *www.scienceexpress.org* /4 September 2008 / Page 1 / 10.1126/science.1165490

- **Web 2.0: CDC invests in Second Life**

- **FDA approves Intel home medical device**

- **"A Lifesaving Checklist" When is it research and when is it quality of care improvement or assessment?**
  - [http://www.irbforum.org/forum/read/2/161/161](http://www.irbforum.org/forum/read/2/161/161)
  - [http://content.nejm.org/cgi/content/full/355/26/2725](http://content.nejm.org/cgi/content/full/355/26/2725)

- **The Tissue-Industrial Complex**
  - Tissue ownership, consent, control and a patient's right to withdraw from tissue research. [www.nytimes.com/2006/04/16/magazine/16tissue.html?_r=2&scp=1&sq=washington%20university%20tissue%20ownership&st=cse&oref=slogin&oref=slogin](http://www.nytimes.com/2006/04/16/magazine/16tissue.html?_r=2&scp=1&sq=washington%20university%20tissue%20ownership&st=cse&oref=slogin&oref=slogin)
Well done is better than well said.

- Benjamin Franklin
Framing the Meeting

• Doug Fridsma
  - Steering Committee Co-chair
  - Associate Professor, Department of Biomedical Informatics, Arizona State University

• Suzanne Markel-Fox
  - Steering Committee Co-chair
  - Director, Strategy & Process Excellence in Drug Development Sciences, GlaxoSmithKline
Meeting Format

- Interactive & Open Discussions
- General & Plenary Sessions
- Facilitated Small Group Breakouts
  - Select scenario (s) beyond your traditional “comfort zone”
  - Each participate in two facilitated breakouts
  - Using representative “real world” (with some overlap) scenarios
  - Encourage high degree of participant interactivity
  - Need volunteers for recorder/reporter to keep notes of discussions and ideas
  - Leave about 15 minutes at the end to allow the recorder to organize his/her thoughts
  - Report outs to the larger groups
Small Group Breakouts

1: Identifying & Evaluating Practice Patterns
2: Identifying Patients to Participate in Research
3: Collecting Data for Mining & Analytics
4: Accessing Research Protocols & Treatment

5: Turning Evidence into Practice
6: Using New and Combined Sources of Data
7: Reporting Adverse Events
8: Supporting Public Health Event Monitoring and Rapid Response Management
Small Group Discussion Questions

Assuming an increasingly evidenced-based, patient-centered, consumer-connected health delivery & learning system:

- What are factors & challenges impacting national policy & role of informatics going forward?
- What are most likely strategies to enhance dissemination, diffusion, & adoption of evidence-based care?
  - For non-academic environments?
  - For safety net providers and their patients?
  - For special populations?
- Scenario-specific questions
The Evidence Continuum

Evidence

Generating  Translating  Disseminating  Applying  Adopting & Refining
The Future State of the Evidence Continuum (Informatics Perspective)

**Barriers/Challenges**
- What are infrastructure, policy, technological, organisational, financial, other obstacles that must be overcome?
- What are likely complications of grid computing, wireless technologies, mobile devices?
- How to engage consumers to help society advance science / create new evidence?
- Is this a US-centric or global issue?
  - Access challenges in under-resourced areas
  - Variations in healthcare systems, healthcare delivery, maturity of HIT

**Evidence**
- Use existing infrastructure to generate new knowledge
- Develop research expertise, sensitivities in practice-based research networks, HIEs
- Integrate, harmonise, standardise, aggregate and manage healthcare data to improve patient care
- Create computable, user-friendly guidelines from healthcare data

**Opportunities**
- What does it take to encourage healthcare providers to use HIT for clinical research that informs clinical practice?
- Create incentives to encourage this development
- Develop registries & public repositories of healthcare data
- What are short- and long-term implications of using new social networks to speed dissemination, evaluation of newly discovered knowledge?
- How do we motivate practitioners to adopt evidence-based care?
- How do we encourage incorporation of evidence-based care into various aspects/levels of healthcare?
AMIA 2008 Board of Directors

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AMIA’s Goals

- **Goal 1:** Support development & implementation of health information technology & a health information infrastructure that will support translational bioinformatics, clinical care, clinical research, public health/population, and personal health management.

- **Goal 2:** Strengthen support for the research infrastructure for health informatics.

- **Goal 3:** Expand size & competency of the health informatics workforce in the US & support continued development of the health informatics profession.

- **Goal 4:** Contribute to development of sound state, federal, & global policy on health information technology issues.

- **Goal 5:** Provide thought leadership & be a catalyst & incubator for new ideas that can be developed by the informatics community.
AMIA Members - 2008

- 4000 members (53 nations)
- Of those indicating an area of interest
  - 74% clinical health care informatics & clinical research informatics
  - 16% public health/population
  - 10% translational bioinformatics
Thank YOU!

American Medical Informatics Association

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