AMIA 2014 Policy Invitational Meeting

Harnessing Next-Generation Informatics for Personalizing Medicine
September 4-5, 2014
Washington Hilton, Washington, DC

Meeting Chair: Peter Tarczy-Hornoch, MD, FACMI, University of Washington
http://www.amia.org/2014-annual-health-policy-invitational-meeting

Purpose
To recommend updates to current policies and to establish a research agenda for the informatics challenges due to changes in our approach to care delivery -- especially as they relate to personalizing medicine through the mining of data from clinical systems (e.g., electronic health records and administrative) and high-volume molecular data (e.g., genomic data and biomarkers) to customize care, target drug development, and ultimately make healthcare more efficient and effective.

Focus and Objectives
The focus of the AMIA 2014 policy invitational meeting will be centered on the informatics opportunities and challenges around personalizing medicine, with an emphasis on areas that are impacted by policy, and policy gaps -- particularly federal laws and regulations. For the purposes of this meeting, we are adapting the Stephen Pauker definition of personalized medicine:

*Personalized medicine is the practice of clinical decision-making such that the decisions made maximize the outcomes that the patient most cares about and minimizes those that the patient fears the most, on the basis of as much knowledge about the individual's state as is available.*

Zak Kohane, in his commentary in *Genome Medicine*, posits the definition as twin questions of “who are you and who do you most resemble?” More narrowly, “the phrase ‘personalized medicine’ is commonly used to refer to genomic medicine, defined as ‘the use of information from genomes (from humans and other organisms) and their derivatives (RNA, proteins and metabolites) to guide medical decision-making.’ Personalized medicine, however, may be defined more broadly to be a model of healthcare that is predictive, personalized, preventive and participatory (‘P4 Medicine’) and that also applies to technologies to customize and deliver care.” For this policy invitational meeting, we are focusing on personalizing medicine specifically using genomic and other high-volume biomolecular data along with data from clinical systems.

2014 invitees will participate in focused and thought-provoking discussions that will weigh the various factors that impact the formulation of a national policy and research agenda around the role of personalized medicine and health informatics in delivering individualized patient care and advancing translational science. The meeting agenda will focus on the policies that support informatics innovations to propel and enable personalizing medicine and high levels of public health.

The AMIA 2014 Policy Invitational Meeting will seek to engage elected federal leaders and their staff as they consider crafting legislation that will support an evolved model of 21st-century drug and treatment development. Federal leaders have made personalized medicine a priority in their strategic objectives as evidenced by the “21st-Century Cures”

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2 http://genomemedicine.com/content/1/1/4
3 Olson S, Beachy SH, Giammaria CF, Berger AC. Integrating Large-Scale Genomic Information into Clinical Practice. The National Academies Press; Washington, DC, USA: 2012.
initiative announced in April of 2014 by House Energy and Commerce Chairman Rep. Fred Upton (R-MI) and committee member Rep. Diana DeGette (D-CO).  

Potential Panel/Breakout Topics

- **Policies governing data access for personalization of care and research.** Topic lead: Nigam Shah
  - Using the data of patients not under direct care (both electronic health record and genomic data):
    - Doctors can't look up the charts of patients who are not under their direct care. In order to personalize care based on what happened to people who resemble you the most (potentially including family members), we may require a change or clarification in the HIPAA privacy rule to allow front-line clinicians to use aggregate patient data for quality improvement purposes. GINA also gives special “status” to genetic and genomic information that precludes its use by insurers and employers. This could impact personalization of care due to imposition of formularies, definitions of medical necessity, etc.
  - Consent for use of data for care and research (both electronic health record and genomic data):
    - Some bioethicists argue that informed consent should not be waived even in cases of clinical equipoise, the uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment used in clinical research. Such a position is incompatible with widespread implementation of personalization based on patient-like-you or point-of-care randomization for research. Alternatively, some have argued that patients have a moral obligation to contribute to the common purpose of improving the quality and value of clinical care in the system. Just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to and facilitate learning.
  - Sharing data across medical record systems: If data are shared how can we maintain research subject privacy while making data available? What is the policy basis for providers and researchers to access data across medical records systems? To what extent should vendors be required to support cross-platform access? How should institutions be incentivized to allow access to data and defining of cohorts across institutions for the purposes of research and discovery?

- **Policies regarding knowledge representation.** Topic lead: Dan Masys
  - Because knowledge about the interpretation of genomic data (and other high volume molecular data), once acquired, is expected to change as scientific understanding grows, electronic health record systems must maintain separation of primary molecular and other similar observations from the clinical interpretation of those observations in a manner that supports future re-annotation and interpretation. This requirement leads to challenges in creating and maintaining the knowledge. Are new policies needed to govern the maintenance and propagation of this changing knowledge?
  - Because the amount of knowledge (and data) exceed the bounds of unaided human cognition, automated decision support tools are needed. Thus both the data and knowledge must be represented in electronic clinical systems in a manner that facilitates automated decision support logic as well as in human-readable (i.e., document) formats. Are new policies needed to ensure standardization of knowledge representation and decision support to support both needs?

- **Policies for data integrity and preservation.** Topic lead: Marc Williams
  - Genomic data have persistent value that extends beyond the lifetime of one individual; this value is expected to grow as scientific understanding grows. These data, if acquired for clinical care purposes and with clinically acceptable quality control, should be maintained indefinitely. Specifically, they should not be destroyed or deleted from electronic clinical records based on more general records preservation rules or at the death of the individual from whom they were obtained. Are new policies needed to support the long-term availability and use of these valuable data?
  - Because a single molecular subunit of either DNA or RNA (a single nucleotide polymorphism) may have important health consequences, all data compression techniques applied to these data must enable full and accurate reconstitution of the original observations (i.e., lossless compression). Are new policies needed to...
needed to ensure the integrity of the original data while still facilitating their practical clinical and research use?

**Anticipated Outcomes**

Anticipated outcomes and/or work products from the meetings include the following in the context of developing policy recommendations and documenting potential dissensions:

- A summary report containing recommendations related to each of the topics covered in the breakout sessions above; and a short-range action and research plan (2-3 years) that can be pursued by the participants and other stakeholders in order to address the issues (getting as close to possible as “AMIA supports the following policies with respect to Integration of Genomic and other high volume biomolecular data into EHRs.”)
- One or more manuscripts suitable for submission to *JAMIA* or elsewhere

**About the AMIA Policy Invitational Meeting**

Since 2006, AMIA has convened an invitation-only health policy meeting to examine the cutting-edge issues in health care and health IT policy from diverse perspectives, air potential challenges and solutions, and offer robust public policy and research-oriented discourse. These meetings are intended to be forward-looking and policy-informing. The overarching objectives are to identify potential future issues, especially those related to the convergence of health IT, clinical technologies, devices, innovations, and communications capabilities; determine areas for further study and research; and develop objective reports synthesizing conference outcomes to inform policymakers about the issues discussed and potential next steps.

For more information about the AMIA Policy Invitational Meeting, please contact Dr. Ross D. Martin, VP of Policy and Development, at ross@amia.org.

**AMIA 2014 Policy Invitational Meeting Planning Committee**

**Peter Tarczy-Hornoch, MD, Chair, University of Washington**

- Suzanne Bakken, PhD, Columbia University
- Chris Chute, MD, Mayo Clinic
- Josh Denny, MD, Vanderbilt University
- Robert Freimuth, PhD, Mayo Clinic
- Chuck Friedman, PhD, University of Michigan
- Rebecca Kush, PhD, Clinical Data Interchange Standards Consortium (CDISC)
- Yves Lussier, MD, University of Arizona
- Dan Masys, MD, University of Washington
- Lucila Ohno-Machado, MD, PhD, UC San Diego
- Casey Overby, PhD, University of Maryland
- Neil Sarkar, PhD, MLIS, University of Vermont
- Nigam Shah, PhD, Stanford University
- Justin Starren, MD, Northwestern University
- Jessie Tenenbaum, PhD, Duke University
- Marc Williams, MD, Geisinger