AMIA Health Policy Conference Series
Final Progress Report

Principal Investigator
Douglas B. Fridsma, MD

Team Member	Role
Susanna Aguirre	AMIA Staff (2013-2014)
Salome Aringo	AMIA Staff (2012-2015)
Patricia Flatley Brennan	201 Policy Invitational Chair
Meryl Bloomrosen	AMIA Staff (2012-2013)
George Hripsack	201 Policy Invitational Chair
Ross D. Martin	AMIA Staff (2013-2015)
Peter Tarczy-Hornock	201 Policy Invitational Chair
Jeffery Smith	AMIA Staff (2015)

The American Medical Informatics Association (AMIA)

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Ellen Makar

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1. **Purpose** (Objectives of Study).
2. **Scope** (Background, Context, Settings, Participants, Incidence, Prevalence).
3. **Methods** (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).
4. **Results** (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications).
5. **List of Publications and Products** (Bibliography of Published Works and Electronic Resources from Study—UseAHRQ Citation Style for Reference Lists).

2014 Report

Introduction and Background

Since 2006, the American Medical Informatics Association (AMIA) convenes an invitational policy meeting to address important, cutting edge, and complex topics at the intersection of health care and informatics. These meetings seek to identify challenges with current policies, make recommendations for future policies, and identify research needs for advancing the topic of focus. Past themes have included: clinical data capture and documentation;[1] health data use, stewardship and governance;[2] and patient-centered care.[3] The 9th Annual AMIA Health Policy Invitational Meeting was held on September 4-5, 2014 at the Washington Hilton in Washington, DC and focused on harnessing next generation informatics for personalizing medicine.
The term personalized—or precision—medicine has multiple related definitions. A systematic review of scientific literature using the terms "personalized" or "individualized" medicine demonstrated how broadly these terms can be interpreted. From biological biomarkers and genomic data to personal preferences, nutrition, lifestyle, and other phenotypic data, all have been referenced as ways to tailor health care to the individual. Indeed, the emergence of "P4 Medicine" embraces the breadth of interpretations by defining a model of healthcare that is predictive, personalized, preventive, and participatory. While it has always been a care provider's primary goal to adjust treatment based on the specific characteristics of a patient, new knowledge and advancements in technology offer expanding opportunities to include a plethora of new types of data for personalizing care.

[1] Cusack CM, Hripcsak G, Bloomrosen M, et al. The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. J Am Med Inform Assoc. 2013;20(1):134-40.

[2] Hripcsak G, Bloomrosen M, Flately Brennan P, et al. Health data use, stewardship, and governance: ongoing gaps and challenges: a report from AMIA's 2012 Health Policy Meeting. J Am Med Inform Assoc. 2014;21(2):204-11.

[3] Flatley Brennan P, Valdez R, Alexander G, et al. Patient-centered care, collaboration, communication, and coordination: a report from AMIA's 2013 Policy Meeting. J Am Med Inform Assoc. Published Online First: 23 Feb 2015 doi:10.1136/amiajnl-2014-003176.

A. Specific Aims

The primary purpose of the 2014 AMIA Health Policy Invitational Meeting was to develop recommendations for future policies, and identify research needs for advancing personalized medicine. Personalized medicine has become an active area of interest at the federal level. The 2008 Presidential Council of Advisors on Science and Technology (PCAST) released a report on *Priorities for Personalized Medicine*. This report highlighted three primary challenges to implementation: technology and tools, regulation, and reimbursement. Technical and policy barriers for achieving a robust health information technology (HIT) ecosystem for enabling personalized medicine were subsequently discussed in the 2010 PCAST report on *Realizing the Full Potential of Health IT (HIT) for Americans: The Path Forward*. A key theme in both reports pertained to the role of regulation to enable advancement of the national HIT infrastructure. To help clarify these issues, the FDA published a report in 2013 on its own role in medical product development that supports personalized medicine. Personalized medicine is at the forefront of health and science policy with the 113/114th House Energy and Commerce Committee's proposed 21st-Century Cures Initiative and the announcement of a Precision Medicine Initiative in President Barack Obama's 2015 State of the Union address. The national attention this area of science has garnered speaks to the importance and relevance of the findings of this policy meeting.

With this growing attention to the importance of personalized medicine, the topic seemed a worthy target for AMIA's dedicated focus through the policy invitational format. For the purposes of this meeting, we adapted 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.

Goals of the Conference

In reaching out to invited participants to the Invitational, AMIA stated the overall purpose of the meeting as the following:

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.

To this aim, we set out to achieve the following goals:

1. To further a national understanding of how the future state of healthcare delivery will increasingly include the use of high-volume molecular data and how the decisions we make relative to the use of informatics will impact that future state

2. To develop informatics-enabled, policy-informing, and research-oriented recommendations on furthering the personalization of medicine and high levels of public health with a view to influence national policy, particularly federal laws and regulations
3. To develop a research agenda that addresses gaps in our understanding of the impact of federal policy on personalizing medicine
4. 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
5. To create a summary report with recommendations; a short-range action/research plan (2-3 years) that can be pursued by the participants and other stakeholders in order to address the issues; and one or more manuscripts suitable for submission to *JAMIA* or a similar publication
6. To create a full report of the meeting after its conclusion

B. Studies and Results

A Policy Invitational Steering Committee consisting of subject matter experts from the AMIA membership was assembled and chaired by Peter Tarczy-Hornoch, Chair, Department of Biomedical Informatics and Medical Education, University of Washington. In addition to the Chair, the PISC included the following individuals (with primary affiliations at the time of the meeting):

- Elmer V. Bernstam, MD, MSE, FACMI, Professor, School of Biomedical Informatics (SBMI) and Department of Internal Medicine (Medical School), University of Texas Health Science Center at Houston
- Chris Chute, MD, Dr PH, Bloomberg Distinguished Professor of Health Informatics, Johns Hopkins University
- Joshua C. Denny, MD, MS, Associate Professor, Departments of Biomedical Informatics and Medicine
- Chuck Friedman, PhD, Director of the Health Informatics Program in the School of Information and Public Health, University of Michigan
- Robert R. Freimuth, PhD, Assistant Professor of Medical Informatics, Department of Health Sciences Research, Mayo Clinic
- Rebecca Kush, PhD, Founder, President and CEO of CDISC.Yves Lussier,MD, Professor of Medicine, University of Arizona
- Daniel Masys, MD, Affiliate Professor of Biomedical and Health Informatics, University of Washington
- Lucila Ohno-Machado, MD, MBA, PhD, Associate Dean for Informatics and Technology and Chief of the Division of Biomedical Informatics, UCSD
- Casey L. Overby, PhD, Faculty Member, Program for Personalized and Genomic Medicine, the Center for Health-related Informatics and Bio-imaging, University of Maryland School of Medicine
- Nigam Shah, MBBS, PhD, Assistant Professor of Medicine, Stanford University
- Justin B. Starren, MD, PhD, FACMI, Associate Professor of Preventive Medicine and Medical Social Sciences, Northwestern University Feinberg School of Medicine
- Jessica Tenenbaum, PhD, Associate Director for Bioinformatics, Duke Translational Medicine Institute (DTMI)

- Marc S. Williams, MD, FAAP, FACMG, Director of the Genomic Medicine Institute, Geisinger
- AMIA staff support was provided by Ross Martin, MD, MHA, VP of Policy and Development, and Susie Aguirre, Policy and Development Specialist.

The committee reviewed existing literature, set the meeting goals, agenda, and invited presenters and attendees. Invitees were selected by the PISC with the intent of having approximately 100 relevant subject matter experts and policy-savvy participants from a wide range of perspectives. The 93 registered attendees included healthcare providers, academicians, technology vendor representatives, industry executives, policy makers, specialty society representatives, consultants, federal regulators, students, patients, caregivers, and AMIA staff.

The core goal of the meeting was to develop policy recommendations and a research agenda to advance the goal of personalizing medicine. Recognizing the broad definition of personalized medicine discussed above, the PISC focused the meeting discussions by limiting the definition of personalized medicine to topics related to personalizing care through the integration of genomic or other high-volume biomolecular data (collectively referred to here as "omics data") with data from clinical systems.

In preparation for the meeting, a designated panel chair provided specific objectives to each presenter along with a packet of pre-reading material and questions that was were also used for small group discussion sessions for all attendees.[4]

The heart of the meeting was a series of facilitated working sessions, which engaged participants in focused, lively discussion on important topics related to personalized medicine in the context of the current health ecosystem. The breakout sessions focused on three primary issues:

1. Policies governing data access for research as well as personalization of clinical care
2. Policy and research needs regarding evolving data interpretation and knowledge representation
3. Policy and research needs to ensure data integrity and preservation

Two keynote presentations provided context on the history of personalized medicine, the state of current knowledge, and insight into future innovations. Panel discussions preceded each of the breakouts to provide context for the discussion and stimulate thinking about the primary issues. These panels were didactic in nature, with each panelist having approximately 15 minutes each for a prepared presentation. At the end of each panel there was a 15 minute period for audience questions. Participants in the breakouts were asked to address questions related to each primary issue. A facilitator led each of the three groups for each of the three breakout sessions (a total of nine breakouts over the course of the meeting), with scribes recording the discussion in each breakout. During a final plenary session, all participants worked together to identify major themes of the meeting, formulate messages for policymakers, and propose next steps and action items.

[4] http://www.amia.org/2014-annual-health-policy-invitational-meeting.

This meeting was funded in part under grant No. R13 HS 1R13HS021825-01, from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. Additional support was provided for the meeting by the following AMIA corporate members: AstraZeneca, Bristol-Myers Squibb, Cerner Corporation, ConvergeHEALTH by Deloitte, GE Healthcare, First Databank, GlaxoSmithKline, Oracle Health Sciences, MEDITECH, Philips, RTI International, and Wolters Kluwer Health. Facilitation services were provided by Deloitte Consulting, LLP.

Overarching Questions

Breakout A: Policies governing data access for research and personalization of care

1. What current policies limit access to and the use of data for personalization of care?
2. What best practices, guidance, or strategies to "get to yes" exist?
3. [If a path to use does not exist] Who should modify the existing policies and what would the wish list for that modification be?
4. What policies exist around consent for re-use of data for personalizing care and enabling research? Are there precedents or analogous policy structures in other domains?
5. What should be the policy basis (and incentives) for providers, patients, and vendors to provide access to data across medical record systems?

Breakout B: Policies regarding knowledge representation

1. Are policies and/or best practice guidelines needed for initial and future re-annotation and interpretation of genomic and other high volume data for clinical purposes, given that annotation and interpretation is expected to change as scientific understanding grows?
2. Are policies and/or best practice guidelines needed to support representing data and knowledge in electronic clinical systems in a manner that facilitates automated decision support logic as well as representation in human-readable formats (i.e., documentation formats)?
3. What is needed to incorporate the approaches from #1 and #2 in health IT environments so that knowledge can be applied to screening, patient management, tracking and reporting?

Breakout C: Policies for data integrity and preservation

1. What policy issues could affect the integrity and persistence of the data needed to achieve the goals of personalizing medicine?
2. What policies are needed to permit data to be safely shared across distributed platforms?
3. What research is needed to identify policy gaps and barriers that impact persistence and integrity of the data and how should this research be funded?

Speakers

Keynotes

Yves A. Lussier, MD, AHSC, BIO5 Institute: *Personalome: current activities and insights*

1. The genome is dynamic (e.g. somatic mutations) and involves more than just genes and genotypes (e.g. copy number variation, epistasis). Even the non-protein coding genome complex as it is critical for gene regulation (e.g. gene expression levels) in ways (e.g. epigenetics) that are not yet fully understood.

2. It is important to balance our genomic knowledge with the human experience (e.g., individuals with male karyotype, who are phenotypically female due to other genetic traits like androgen insensitivity syndrome).

Philip E. Bourne, PhD, National Institutes of Health: *NIH as a digital enterprise*

1. There are concerns about the reproducibility and sustainability of research in the current environment. Change is needed.
2. Initiatives like the NIH Commons and cloud-based access to shared big data resources (computational and data sources), are potential approaches to creating sustainable infrastructure in support of alternate business models.

Panel A: Policies governing data access for research and personalization of care

Patrick Ryan, PhD, Janssen Research: *Policies governing data access for personalization of care and research*

1. Patients deserve personalized evidence to improve the quality of their care. Establishing the reliability of real-world evidence is a necessary prerequisite for a learning health system.
2. Patient-level predictions of personalized evidence require big data, but do not necessarily require exposing patient-level data.

Erin Holve, PhD, Academy Health: *What we talk about when we talk about HIPAA*

1. Local interpretations of HIPAA privacy provisions are highly varied and may be incorrect. This lack of clarity can be improved by sharing best-practices.
2. Consent needs to be reimagined and reengineered to better engage and empower patients and families to manage and share their data.

Bradley Malin, PhD, Vanderbilt University: *Personalization and data protection: policies, pitfalls, and opportunities*

1. There are concerns about the reproducibility and sustainability of research in the current environment. Change is needed.
2. Initiatives like the NIH Commons and cloud-based access to shared big data resources (computational and data sources), are potential approaches to creating sustainable infrastructure in support of alternate business models.

Panel B: Policies regarding knowledge representation

Brian D. Athey, PhD, University of Michigan: *tranSMART and the emergent requirement for policies of knowledge representation and sustainment in translational research*

1. There are multiple methods for standardizing knowledge through the use of common data models (e.g., OMOP) and/or through standard data terminologies (e.g., SNOMED, LOINC, etc.).
2. Private-public partnerships and open data projects are essential for bringing together expertise, experience, and resources that are not possible when working independently.

John Ioannidis, MD, PhD, Stanford University: *Policies regarding knowledge representation*

1. There are no standard methods for interpreting genomic data, making it difficult to incorporate these data into clinical care.
2. The clinical efficacy, effectiveness, and cost-effectiveness of genomic-guided decision support are largely unknown.

Thomas Scarnecchia, MS, Digital Aurora: *Policies regarding knowledge representation*

1. It is unclear how well the appropriate terminologies cover the molecular diagnostics available today (e.g., LOINC codes for clinically available genetic tests).
2. Many institutions keep their genomic data repositories separate from their EHR platform. Perhaps there is the opportunity to use common data frameworks to allow for sharing and distributed analytics.

Panel C: Policies for data integrity and preservation
Betsy L. Humphries, National Library of Medicine: *Data integrity and preservation*

1. Preservation of digital data equates to permanent access; in contrast to clinical data, lost genomic data may be easier to recreate.
2. Robust metadata need to be collected and retained along with genomic testing data or clinical data to allow for meaningful use of those data in the future.

Laura Rodriguez, PhD, NHGRI: *Policies to support data needs: questions for genomic data sharing*

1. The greatest public benefit can be achieved if genomic data are made available—under terms consistent with participant informed consent—in a timely manner and to the largest possible number of investigators.
2. In preserving patient privacy, we need to move away from thinking only about preventing inappropriate data access and include more explicit attention toward enabling appropriate data use.

Clay B. Marsh, MD, The Ohio State University: *The ecosystem of personalized medicine: using complex systems approaches to find weak signals in data*

1. To fully realize personalized medicine, we need vast amounts of data to identify small signals. This is only possible within the context of interoperable data sharing.
2. We need the right integrative tools to make sense of the data. Viewing the data through different lenses allows for important insights that might otherwise be hidden.

After the conclusion of the Policy Invitational, several members of the PISC worked with the AMIA staff and Laura Wiley, a PhD candidate in genetics and medical informatics at Vanderbilt University, to compile the extensive notes from the meeting into findings and recommendations. These preliminary findings and recommendations were presented at the AMIA 2014 Annual Symposium[5] and then reviewed and refined by the PISC. The findings and recommendations were further refined into a paper that was submitted for publication in *JAMIA*. The paper has been accepted for publication, but has not yet been published.

C. Significance

There is ambiguity in the legislative and regulatory language and wide variation in the interpretation of legislation and regulation on the differences between quality improvement (QI) and research. Activities that involve the use of data collected from humans are regulated by multiple rules. In simplified terms, information sharing activities related to treatment, payment and operations are permitted under the Health Insurance Portability and Accountability Act of

[5] Harnessing next-generation informatics for personalizing medicine: report from the 2014 AMIA Health Policy Invitational Meeting. AMIA 2014 38th Annual Symposium. November 19, 2014. http://knowledge.amia.org/amia-58416-annual-1.1540268/t-002-1.1540328/f-s101-1.1836227/s101-1.1836228/s101-1.1836229?qr=1.

1996 (HIPAA) privacy rule. Most internally focused QI initiatives do not fall under the Federal Policy for Protection of Human Subjects ("Common Rule") but are considered part of health care operations under HIPAA and hence do not need review by an institutional review board (IRB). However, a problem arises when a QI initiative yields generalizable findings that would ideally be shared with the broader healthcare community. When one desires to publish the findings of a finished QI project, the work is then considered to be research and is subject to the Common Rule, thereby necessitating IRB review. Further, depending on the actual data items used, HIPAA may or may not apply, possibly restricting the use of protected health information (PHI). This circumstance leads to significant confusion about how to apply these rules and results in lost opportunities for shared learning among healthcare institutions.

Recommendations:

1. Congress should consider the recommendation of the AMIA Public Policy Committee to "[amend] the HIPAA definition of health care operations to include 'non-interventional research' (e.g., research utilizing previously collected data) as an appropriate operational use of PHI."
2. The U.S. Department of Health and Human Services (HHS) should clarify pathways for work originally undertaken as QI to transition into a research designation and undergo IRB review, thus facilitating broader dissemination of learning at multiple institutions.
3. Move toward centralized IRBs (for example, www.irbshare.org) to address the differing interpretations of overlapping privacy laws, reduce the inconsistency of IRB review and reduce the overall review burden as the number of studies increase.

Patient perceptions of the risk/benefit tradeoff in data sharing was identified by meeting participants as a key challenge, in part due to highly publicized data breaches disclosed under the modified HIPAA and the Genetic Information Nondiscrimination Act reporting requirements.[6] Positively, in prior surveys >80% of participants indicated that they would allow their health information to be shared among their providers.[7] Additionally, in a study from the UK, 62% of respondents supported the use of EHRs for care provision, planning, and research; about 28% of respondents were undecided.[8] Among the undecided group, 80% supported use for research, and 67% preferred the use of de-identified data.

Recommendations:

1. Convene an expert panel (consisting of representatives from various groups including: AMIA, the American Society for Human Genetics, and the American College of Medical Genetics) to determine which metadata elements are crucial to allow for reinterpretation and reanalysis of genomic or other high-volume data as required minimum data sets.

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[6] U.S. Department of Health and Human Services. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act. http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf.

[7] Simon SR, Evans JS, Benjamin A, Delano D, Bates DW. Patients' attitudes toward electronic health information exchange: qualitative study. J Med Internet Res. 2009;11(3):e30.

[8] Luchenski SA, Reed JE, Marston C, Papoutsi C, Majeed A, Bell D. Patient and public views on electronic health records and their uses in the United kingdom: cross-sectional survey. J Med Internet Res. 2013;15(8):e160.

2. Research is needed to assess the adequacy and/or need to adapt existing terminologies and ontologies for capture of both metadata elements and the interpretations of these data.
3. Return of genomic or high-volume biomolecular data in the form of PDFs should be discouraged. Return of results in a computer-readable format that contains the appropriate metadata as determined by the expert panel should be considered the minimum standard for data reporting and should use standardized terminologies and ontologies whenever possible.
4. Identify data governance standards to allow for storage of raw data outside of clinical information systems. Develop policies regarding required levels of clinical relevance before release of these data into the medical record.

It is important to decouple omics data from clinical information systems and retain some form of the raw data in structured and standardized forms. Knowledge about both the analysis and interpretation of omics data, once acquired, is expected to change as scientific understanding grows. Currently, omics data interpretations can be returned as reports (e.g., Portable Document Format files) that do not allow for reanalysis or reinterpretation. The raw data underlying these reports are usually unavailable to either the ordering provider, patient, or payer. Unfortunately, it is presently unclear what forms of raw data (e.g., variant data) and metadata (e.g., what was measured, how it was analyzed) should be retained. Additionally, underutilization of standardized terminologies and ontologies to describe both the raw data and interpretations hamper consistent interpretation of results across different testing centers. Many institutions have found, that it is not feasible to store these data in the clinical information systems due to both size and variable clinical utility at the time of data collection.

Recommendations:

1. Convene an expert panel (consisting of representatives from various groups including: AMIA, the American Society for Human Genetics, and the American College of Medical Genetics) to determine which metadata elements are crucial to allow for reinterpretation and re-analysis of genomic or other high-volume data as required minimum data sets.
2. Research is needed to assess the adequacy and/or need to adapt existing terminologies and ontologies for capture of both metadata elements and the interpretations of these data.
3. Return of genomic or high-volume biomolecular data in the form of PDFs should be discouraged. Return of results in a computer-readable format that contains the appropriate metadata as determined by the expert panel should be considered the minimum standard for data reporting and should use standardized terminologies and ontologies whenever possible.
4. Identify data governance standards to allow for storage of raw data outside of clinical information systems. Develop policies regarding required levels of clinical relevance before release of these data into the medical record.

There are ethical, legal, and social considerations that need to be addressed surrounding the (re-)use and (re-)interpretation of data. Genomic data, in particular, has value across the lifetime of a patient. Although technical innovations make it increasingly feasible to measure these data repeatedly, a single measurement of these data maintains more value than is typical of other health data. At present, most of these tests are analyzed a single time and are siloed at the collecting institution unless the patient requests their health records. However, as previously

stated, many of the institutions collecting genomic data do not store these data in a patient's medical record due to the large volume and variable clinical utility of these data. If these data are not part of the patient's medical record, it is unclear whether the HIPAA record access provisions apply. Should those provisions apply to medically collected biomolecular data, additional clarification is needed to determine the level of "raw" data the patient is entitled access (e.g., sequence reads vs. all genotype vs. variant list). Drawing from other types of medical data, if genomic data are treated like imaging data, a patient should have access to the raw information reported by the instrument, allowing for complete reanalysis and interpretation by an outside source. However if genomic data were treated like other laboratory tests, simply returning the final genotype calls would be sufficient (e.g., laboratory tests that make use of mass spectrometry only report the analyte of interest, rather than the entire mass spectrum). Regardless of the patient's right to access these data, we know that the As discussed above, the interpretation of these data will evolve over time. and it is unclear at present who bears ethical and legal obligations to perform this reanalysis and inform patients with this updated information.

Recommendations:

1. Develop guidance on who bears legal responsibility for the re-annotation of genomic and high volume-biomolecular data. Specific questions that need to be addressed include the length of time and frequency of re-annotation required, definition of who should be contacted with the new information (ordering physician, primary care physician, patient), and procedures for instances where the contact person or patient cannot be found.
2. Although HIPAA makes it clear that patients have a right to a copy of the content of their medical records, given previous recommendations to keep raw or non-clinically relevant biomolecular data outside of clinical information systems, clarification of a patient's right to these raw data are needed.

Errors in medical records present significant barriers to delivering personalized medicine and to the realization of a learning healthcare system. Accurate health records are necessary for delivering personalized medicine and for realizing a learning healthcare system in which current medical information is used to inform future treatment decisions. Under current legal guidelines, medical record data cannot be altered to remove errors. Instead care providers may add information in the form of an amendment that identifies and corrects the error. While this approach is usually sufficient for traditional patient care, This form of error correctionit can be problematic for personalizing medicine for two reasons. First, many of the methods used to personalize medicine rely on computer algorithms processing medical record data. Many of these algorithms rely on keywords and are not sufficiently advanced to identify corrections in the form of amendments. At present it is unclear how frequent this type of error is and what what impact it has on downstream analyses of medical record data. Secondly, from the single patient perspective, requiring a healthcare provider intermediary for error correction can be fraught with challenges. Many providers are unwilling/unable to correct errors in documentation created by other providers, or simply forget to correct these errors given the increasingly high workload from increasing documentation requirements.

Errors in health records are problematic for the care of individual patients and present significant barriers to the reuse of data. Under current legal guidelines, however, medical record data cannot be changed and errors cannot be removed. Corrections must be made by clinicians and take the

form of amendments to the data; this requirement complicates the collection, use, and interpretation of the data.

Recommendations:

1. Conduct research to better understand the impact of errors on secondary usesreuse of medical records, especially those types of data that are most likely to be used as part of a learning healthcare system for the diagnosis, treatment, and prevention of disease. Methods that help to prevent the introduction of errors in medical record data should be identified, including the development of standardized documentation practices that facilitate the secondary use reuse of these data and standardized consent language that provides uniformity across studies and institutions.
2. Engage in a national discussion on the rights of patients to go beyond reading their medical records as assured by HIPAA, to having the ability to add data to their record to identify and correct errors (through amendments) without going through a physician intermediary as is the current custom. access and suggest corrections to their own medical records. As part of this discussion, policies and responsibilities regarding the correction of errors in medical records should be clarified. Additionally, policies that outline the responsibilities of health care providers to collect, store, maintain, and use patient-provided data should be reviewed.

To more effectively practice personalized medicine using omics data, researchers must have access to large patient data sets, which are most efficiently assembled through the sharing of data among multiple institutions (requiring mechanisms for unique patient identification or other record matching techniques[9]). The provisions outlined in HIPAA for sharing de-identified and limited data sets are often used by institutions to govern what data can be shared. There are concerns, however, whether omics data should be considered a "biometric identifier" that would be excluded from data sharing initiatives under the current policy. HIPAA. If these data were classified as PHI, a number of NIH data sharing mandates (e.g., NIH database of Genotypes and Phenotypes – dbGaP) would be problematic for EMR-linked biobanks. Additionally, there are also privacy concerns for the large data sources, currently legal protections related to the potential misuse of clinical data are not transferable to de-identified data sets under current guidelines. Further, mandates requiring broad data sharing create privacy concerns for patients who may otherwise desire to share their data with local researchers, but not be comfortable with broader use of their data.Many of these de-identified data sets are required to be shared in public repositories (e.g., NIH database of Genotypes and Phenotypes – dbGaP) by government funding agencies. This creates privacy concerns for individuals who may otherwise desire to share their data with local researchers, but not be comfortable with broader use of their data.

Recommendations:

1. Congress and/or HHS should clarify the application of HIPAA guidelines to data sets that might be considered to be biometric identifiers, such as genomic data, which may be impossible to fully de-identify without destroying their integrity and usefulness. If omic data sets are considered to be a biometric identifier, then an alternative mechanism should

[9] Hripcsak G, Bloomrosen M, Flately Brennan P, et al. Health data use, stewardship, and governance: ongoing gaps and challenges: a report from AMIA's 2012 Health Policy Meeting. J Am Med Inform Assoc. 2014;21(2):204-11.

be described through which these data could be shared; the applicable regulations should be updated accordingly.
2. Augment legal protections to safeguard de-identified data and allow for the prosecution of those who misuse de-identified data. In particular, specific prohibitions should be enacted against the attempted re-identification of subjects.

D. Plans / 2015 Meeting

Dr. Thomas H. Payne is the Steering Committee Chair for the 2015 AMIA Invitational Policy meeting, which will be held on September 16-17th in Washington, DC. Preliminary planning efforts are well underway and AMIA is making arrangements to include a larger number of consumer/patient representatives. The topic of the 2015 AMIA Invitational Policy Meeting is ***Unlocking the Potential of Electronic Health Records: How Policymakers Can Impact the On-going Evolution of EHRs.***

In response to prior feedback, AMIA invited patient advocates to attend and be acknowledged as patient participants in the meeting. Approximately 160 attendees were invited to register for the event from five major categories of participants: government, industry, academia, policy experts and patient advocates. Those registered in the five categories are tallied below. As with all conferences, some registered attendees had cancellations at the last minute (including the Chair of the meeting, who had a family emergency and had to phone his opening comments in via teleconference. Neil Sarkar served as guest emcee in Dr. Tarczy-Hornoch's place.

	Government	Industry	Academia	Policy	Patient Advocate
Accepted	17	24	31	11	3

* Excludes 6 staff attendees.

There was some attrition on the final day of the meeting. This attrition did not impact the quality of the discussion significantly, but it did result in a number of meals wasted. AMIA investigated an alternative approach to registration for the 2015 meeting as a result and planned to charge a nominal fee to invited registrants to cover a portion of the cost of food and beverage.

E. Publications

The formal report from the 2014 Policy Invitational Meeting has been submitted to and accepted for publication by the Journal of the American Medical Informatics Association. The manuscript ID is amiajnl-2015-003755.R2. The title is "Harnessing next-generation informatics for personalizing medicine: a report from AMIA's 2014 Health Policy Invitational Meeting." Publication date has not been announced.

F. Project-Generated Resources

Copies of the meeting materials--including a briefing document, discussion and breakout questions, and an annotated list of recommended reading are available on the AMIA website: https://www.amia.org/2014-annual-health-policy-invitational-meeting

In anticipation of the policy conference, Dr. Ross Martin, former AMIA VP of Policy and Development, conducted a series of filmed interviews on the topic of personalizing medicine at various AMIA meetings. The produced video was shared with participants in advance of the meeting and shown at the opening of the conference. The video is posted on the meeting link above and is also available on Vimeo: https://vimeo.com/104677371