Harnessing next-generation informatics for personalizing medicine: a report from AMIA's 2014 Health Policy Invitational Meeting

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ABSTRACT

The American Medical Informatics Association convened the 2014 Health Policy Invitational Meeting to develop recommendations for updates to current policies and to establish an informatics research agenda for personalizing medicine. In particular, the meeting focused on discussing informatics challenges related to personalizing care through the integration of genomic or other high-volume biomolecular data with data from clinical systems to make health care more efficient and effective. This report summarizes the findings ($n = 6$) and recommendations ($n = 15$) from the policy meeting, which were clustered into 3 broad areas: (1) policies governing data access for research and personalization of care; (2) policy and research needs for evolving data interpretation and knowledge representation; and (3) policy and research needs to ensure data integrity and preservation. The meeting outcome underscored the need to address a number of important policy and technical considerations in order to realize the potential of personalized or precision medicine in actual clinical contexts.

Keywords: translational bioinformatics, health policy, precision medicine, medical informatics, learning health care system

INTRODUCTION AND BACKGROUND

Each year, 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 from September 4–5, 2014 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 demonstrates 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.[4] Indeed, the emergence of "P4 Medicine" embraces the breadth of interpretations by defining a model of health care that is predictive, personalized, preventive, and participatory.[5] 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.

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*.[6] This report highlighted 3 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*.[7] 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.[8] Personalized medicine is at the forefront of health and science policy with the 113th/114th House Energy and Commerce Committee's proposed 21st-Century Cures Initiative[9] and the announcement of a Precision Medicine Initiative in President Barack Obama's 2015 State of the Union address.[10] The national attention this area of science has garnered speaks to the importance and relevance of the findings of this policy meeting.

MEETING STRUCTURE AND PURPOSE

A Policy Invitational Steering Committee (PISC; see acknowledgments) consisting of subject matter experts from the AMIA membership was assembled and chaired by Peter Tarczy-Hornoch, chair of the Department of Biomedical Informatics and Medical Education at the University of Washington. 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 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

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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 prereading material and questions that were also used for small group discussion sessions for all attendees.[11] The meeting was convened on September 4–5, 2014 in Washington, DC. The 93 registered attendees included health care providers, academicians, technology vendor representatives, industry executives, policy makers, specialty society representatives, consultants, federal regulators, students, patients, caregivers, and AMIA staff.

Two keynote presentations provided context on the history of personalized medicine, the state of current knowledge, and insight into future innovations. Panel presentations prior to each of the 3 breakout sessions provided a more specific view on the policy and research challenges surrounding 3 primary areas of focus: (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; and (3) policy and research needs to ensure data integrity and preservation.

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.

A summary of the meeting presentations is given in table 1. Following the question period for each panel, there were three ~90-minute breakout sessions which divided the attendees into 3 smaller discussion groups to address specific questions developed by the PISC (presented in table 2). Each set of small group discussions were followed by a report out and further reflection and discussion by the group at large. Following the meeting, notes taken by scribes throughout the meeting were summarized and synthesized by the authors to develop policy findings and recommendations. These preliminary findings and recommendations were presented at the AMIA 2014 Annual Symposium[12] and then reviewed and refined by the PISC.

FINDINGS AND RECOMMENDATIONS

Key findings and recommendations from the meeting participants were further refined by the authors and are summarized below. Recommendations for each set of findings are further detailed in table 3.

Policies governing data access for research and personalization of care

Finding: 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 1996 (HIPAA) privacy rule.[18] Most internally focused QI initiatives do not fall under the Federal Policy for Protection of Human Subjects ("Common Rule")[19] 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 health care 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 health care institutions.

Recommendations (see table 3):

1. *Classify non-interventional research as appropriate use of PHI under HIPAA regulations.*
2. *Create mechanisms to transition QI projects to research designations.*
3. *Move toward centralized IRB solutions.*

Finding: Patients play a vital role in personalizing medicine by providing specific and general consent for use of their data for others' benefit.

Patient perceptions of the risk/benefit tradeoff in data sharing was identified as a key challenge by meeting participants, due in part to highly publicized data breaches disclosed under the modified HIPAA and the Genetic Information Nondiscrimination Act reporting requirements.[20] Positively, in prior surveys, > 80% of participants indicated that they would allow their health information to be shared among their providers.[21] Additionally, in a study from the UK, 62% of respondents supported the use of electronic health records for care provision, planning, and research while about 28% of respondents were undecided.[22] Among the undecided group, 80% supported use for research and 67% preferred the use of deidentified data.

Recommendations (see table 3):

1. *Using public education funds from the Department of Health and Human Services to develop public awareness campaigns to accurately communicate benefits and risks of data sharing.*
2. *Harmonize state and federal laws on consent requirements to reduce the burden placed on patients who are willing to share their data.*

Policy and research needs for evolving data interpretation and knowledge representation

Finding: 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 (eg, Portable Document Format files) that do not allow for reanalysis or reinterpretation.[23] 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 (eg, variant data) and metadata (eg, 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.[24,25] 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.[26,27]

Recommendations (see table 3):

1. *Convene a standing expert committee to identify necessary metadata elements for omic data reanalysis and reinterpretation as new technologies emerge.*
2. *Research adequacy of existing ontologies and identify additional needs to capture omics-related metadata and interpretations.*
3. *Require that omics data be returned in computer-readable formats as part of the Clinical Laboratory Improvement Amendment certification.*

Table 1: Summary of presentations

	Title/Speaker	Key Findings
Keynotes	Personalome: Current Activities and Insights *Yves A Lussier, MD*	1. The genome is dynamic (eg, somatic mutations) and involves more than just genes and genotypes (eg, copy number variation, epistasis). Even the nonprotein coding genome is complex, as it is critical for gene regulation (eg, gene expression levels) in ways (eg, epigenetics) that are not yet fully understood. 2. It is important to balance our genomic knowledge with the human experience (eg, individuals with male karyotype who are phenotypically female due to other genetic traits like androgen insensitivity syndrome).
	NIH as a Digital Enterprise *Philip E Bourne, PhD*	1. Digitization and rapid data growth have the promise of being disruptive to biomedical research and health care as they have been in other industries. Part of that disruption leads to concerns about the reproducibility and sustainability of research. 2. Change is needed. Initiatives like the NIH Commons and cloud-based access to shared big data resources (computational and data sources), along with different business models, are potential approaches that can effect change and create a sustainable infrastructure that better supports reproducible research.
Panel A: Policies Governing Data Access for Research and Personalization of Care	Policies governing data access for personalization of care and research *Patrick Ryan, PhD*	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.
	Personalization & Data Protection: Policies, Pitfalls, & Opportunities *Bradley Malin, PhD*	1. Risk analysis for deidentification is possible, but there are no agreed-upon standards. We need a national clearinghouse of models, methods, and evaluations within the context that protections should be proportional to potential for harm. 2. It is possible to perform secure computations over health data such that no patient-level records are revealed. To achieve such goals, however,the health care community must agree upon the infrastructure for such activities, including who gets to manage the keys, who performs the functions over the data, and where the data is stored during the process.
	What We Talk About When We Talk About HIPAA *Erin Holve, PhD*	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.
Panel B: Policies Regarding Knowledge Representation	tranSMART & the Emergent Requirement for Policies of Knowledge Representation and Sustainment in Trans. Research *Brian D Athey, PhD*	1. There are multiple methods for standardizing knowledge through the use of common data models (eg, OMOP) and/or through standard data terminologies (eg, 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.
	Policies regarding knowledge representation *John Ioannidis, MD, PhD*	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.
	Policies regarding knowledge representation *Thomas Scarnecchia, MS*	1. It is unclear how well the appropriate terminologies cover the molecular diagnostics available today (eg, 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	The ecosystem of personalized medicine: using complex systems approaches to find weak signals in data *Clay B Marsh, MD*	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. We also need to use the meaningful data to create analytic tools of the future that may more easily extract this data and ultimately give us the right lens to see only signals in the future.
	Data integrity and preservation *Betsy L Humphries*	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.
	Policies to support data needs: questions for genomic data sharing *Laura Rodriguez, PhD*	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.

Abbreviations: NIH, National Institutes of Health; OMOP, Observational Medical Outcomes Partnership; SNOMED, systematized nomenclature of medicine; LOINC, logical observation identifiers names and codes; HIPAA, Health Insurance Portability and Accountability Act; EHR, electronic health record.

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Table 2: Breakout discussion 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? • What best practices, guidance, or strategies to "get to yes" exist? • [If a path to use does not exist], who should modify the existing policies and what would the wish list for that modification be? 2. What policies exist around consent for reuse of data for personalizing care and enabling research? Are there precedents or analogous policy structures in other domains? 3. 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 reannotation 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 (ie, documentation formats)? 3. What is needed to incorporate the approaches from Nos. 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?

4. *Identify data governance standards to keep raw biomolecular data separate from clinical information systems.*

Finding: 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 (eg, 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 (eg, 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 interpretation of these data will evolve over time. At present, it is unclear who bears ethical and legal obligations to perform this reanalysis and inform patients with this updated information.

Recommendations (see table 3):

1. *Define who bears ethical and legal responsibilities for reanalysis of raw data.*
2. *Clarify the patient's right under HIPAA to access raw biomolecular data collected by care providers when those data are not stored in the medical record.*

Policy and research needs to ensure data integrity and preservation

Finding: Errors in medical records present significant barriers to delivering personalized medicine and to the realization of a learning health care system.

Accurate health records are necessary for delivering personalized medicine and for realizing a learning health care 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 amending errors this way is usually sufficient for traditional patient care, it can be problematic for personalizing medicine. 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 impact it has on downstream analyses of medical record data. Secondly, from the patient perspective, requiring a health care provider intermediary for amendment and error correction can be fraught with challenges. Many providers are unwilling or unable to amend documentation from other providers, or they simply forget to enter the amendment given the high workload from increasing documentation requirements.

Recommendations (see table 3):

1. *Conduct research on the impact of documentation errors on the reuse of medical record data by computational methodologies.*
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 the record to identify and correct errors*

Table 3: Summary findings and recommendations

Topic	Findings	Recommendations
Policies governing data access for research and personalization of care	*There is ambiguity in the legislation and regulatory language and wide variation in the interpretation of legislation on the differences between quality improvement (QI) and research.*	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' (eg, research utilizing previously collected data) as an appropriate operational use of PHI."[13] 2. The US Department of Health and Human Services (HHS) should clarify pathways for work originally undertaken as QI to transition into a research designation and undergo institutional review board (IRB) review, thus facilitating broader dissemination of learning at multiple institutions.[14] 3. Entities overseeing research should move toward centralized IRBs (eg, 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.
	Patients play a vital role in personalizing medicine by providing specific and general consent for use of their data for others' benefit.	1. HHS (through its public education budget) or other stakeholders should fund public awareness campaigns to better communicate the actual benefits and risks of sharing medical data. Numerous tools for such a campaign have been developed (or are being developed).[15,16] 2. Federal and state regulators should harmonize or at least clarify the various federal and state restrictions on obtaining patient consent for the sharing of genomic data. Current models in use are opt-out, broad consent (as advocated by the NIH Genomic Data Sharing Policy), or project-specific consent. Currently, as patients move around the country, they are subject to different consent laws that create confusion and additional burden. Resources such as the Participant-Centered Consent Toolkit[17] can be leveraged to ensure that managing consent for data sharing does not become onerous on the patient.
Policy and research needs for evolving data interpretation and knowledge representation	*It is important to decouple genomic or high-volume data from clinical information systems and retain some form of the raw data in structured and standardized forms.*	1. HHS (through AHRQ, NLM, or CMS) or another convener should establish a standing 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. 2. Researchers should assess the adequacy and/or need to adapt existing terminologies and ontologies for the capture of both metadata elements and the interpretations of these data. 3. Laboratories should return genomic or high-volume biomolecular data in a computer-readable format (rather than PDF) that contains the appropriate metadata as determined by the aforementioned expert panel. This format should be considered the minimum standard for data reporting and should use standardized terminologies and ontologies whenever possible. 4. Industry stakeholders should identify data governance standards to allow for storage of raw data outside of clinical information systems and 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.	1. Regulators should develop guidance on who bears legal responsibility for the reannotation of genomic and high-volume biomolecular data. Specific questions that need to be addressed include the length of time and frequency of reannotation 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. The HHS Office of Civil Rights should clarify the patient's rights—consistent with their HIPAA-based rights to a copy of the content of their medical record—to access their raw and nonclinically relevant biometric data that are kept outside of clinical information systems (as previously recommended).
Policy and research needs to ensure data integrity and preservation	*Errors in medical records present significant barriers to delivering personalized medicine and to the realization of a learning health care system.*	1. Researchers should conduct studies on the impact of errors on the reuse of medical records, especially those types of data that are most likely to be used as part of a learning health care 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 reuse of these data and standardized consent language that provides uniformity across studies and institutions. 2. Industry stakeholders should engage in a national discussion on the rights of patients to have 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. These amendments should be flagged as patient-initiated, just as other patient-generated data are typically flagged. 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.
	Ambiguities in regulations that govern the sharing of patient data must be clarified.	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 deidentify without destroying their integrity and usefulness. If omic data sets are considered to be a biometric identifier, then an alternative mechanism should be described through which these data could be shared; the applicable regulations should be updated accordingly. 2. Federal legislators or regulators should augment legal protections to safeguard deidentified data and allow for the prosecution of those who misuse deidentified data. In particular, specific prohibitions should be enacted against the attempted reidentification of research subjects.

Abbreviations: AMIA, American Medical Informatics Association; HIPAA, Health Insurance Portability and Accountability Act; PHI, protected health information; NIH, National Institutes of Health; AHRQ, Agency for Healthcare Research and Quality; NLM, National Library of Medicine; CMS, Centers for Medicare and Medicaid Services; PDF, Portable Document Format.

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without going through a physician intermediary, as is the current custom.

Finding: Ambiguities in regulations that govern the sharing of patient data must be clarified.

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—a key focus of the AMIA 2012 Health Policy Invitational[2]). The provisions outlined in HIPAA for sharing deidentified 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 HIPAA. If these data were classified as PHI, a number of National Institutes of Health (NIH) data sharing mandates (eg, NIH database of Genotypes and Phenotypes—dbGaP[28]) would be problematic for electronic medical records–linked biobanks. 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 deidentified data sets. Further, mandates requiring broad data sharing create privacy concerns for patients who may otherwise desire to share their data with local researchers but may not be comfortable with broader use of their data.

Recommendations (see table 3):

1. *Clarify whether omics data are considered biometric identifiers under HIPAA.*
2. *Augment legal protections to safeguard deidentified data from misuse and attempted reidentification of subjects.*

CONCLUSION

The anticipated benefits of personalized medicine have brought the field to the forefront of biomedical research as well as health and science policy. The 2014 AMIA Health Policy Invitational Meeting focused on topics related to using omics data integrated with data from clinical systems to personalized care. Realizing the potential of personalized medicine and moving it from demonstration projects to routine clinical care will require addressing a number of important policy and technical considerations. The policy recommendations emerging from the meeting underscores the need for thoughtful policymaking to advance the incorporation of omics data into contemporary medicine for the ultimate development of an integrated learning health care system that epitomizes the promise of precision medicine.

CONTRIBUTORS

LKW and PT contributed equally. All authors contributed to the summarization and synthesis of meeting notes as well as writing, reviewing, and approving this manuscript.

COMPETING INTERESTS

None.

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