AMIA PUBLIC POLICY PRINCIPLES AND POLICY POSITIONS

2016 – 2017 Priorities
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PREFACE

Increasingly, the science and tools of informatics are being leveraged across all levels of healthcare delivery, public health and clinical research. The digitization of data across the health and research enterprise has thrust a traditionally academic pursuit more firmly into everyday application. Healthcare delivery now relies on electronic health records (EHRs); regulated medical devices and pharmaceutical drug development increasingly use a host of real-world data to demonstrate safety and effectiveness; epidemiologists have the capacity to leverage untold sources of data with the advent of the Internet of Things; and clinical research can now rely on vast databases as part of the Big Data revolution. Informatics is foundational to each and every one of these transformations.

Over the last nine months, AMIA’s Public Policy Committee has considered the present and near-term policy landscape to develop Principles and Positions across select, priority domains, which are essential to the emergent realm of public policy referred to as Health Informatics Policy. Similar to Environmental Policy, Education Policy and Social Policy, Health Informatics Policy is a distinct policy domain which seeks to optimize care delivery & care experience, improve population and public health, and advance biomedical research through the collection, analysis and application of data.

AMIA Public Policy identified six initial pillars as core to Health Informatics Policy, including: Patient Empowerment, Health IT Safety, Workforce and Education, Data Sharing in Research, Biomedical Data Standards & Interoperability, and Informatics-Driven Quality Measurement. This consolidated document includes the first four identified domains, with work on the remaining two ongoing.

Each priority begins with a series of statements describing what AMIA believes – Principles that describe the values intrinsic to the pillar and viewed through an informatics lens. A series of Policy Positions are resultant from these Principles, and they are supported through evidence in peer-reviewed literature. We worked diligently to represent AMIA’s Core Values by convening interdisciplinary sub-groups to develop each evidence-based position through a consensus process.

We are hopeful that these Principles and Positions will help AMIA articulate to its members, policymakers and other stakeholders those issues and conversations we hold with highest import. Over the next several months, the Public Policy Committee will continue its work to define the core of Health Informatics Policy, and we will continue our brand of evidence-based policy recommendations – supported by the latest research and reinforced through the literature – so that policymakers may benefit not just from what our members know, but from what they do.
PATIENT EMPOWERMENT

AMIA Believes:

<table>
<thead>
<tr>
<th>AMIA Policy Principles</th>
<th>Policies, programs, research and care delivery should seek to empower patients through access to, and control of, their personal health information.</th>
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<td>Health informatics is key to enabling delivery of patient-centered care.</td>
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<td>Patients must play a vital role in the development of public policy as well as publicly-funded programs &amp; research.</td>
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Based on these Principles, AMIA Supports:

1. Efforts that enable patients to access and transmit all data contained in their electronic health record, rather than a limited or pre-defined set of data, to improve availability of data for care delivery, biomedical discovery, and in support of patients’ own health and wellness.

2. Technology-enabled approaches that encourage patients to review and contribute directly to their record, which has been shown to improve their understanding of their own health information, lead to improved self-care, increase the likelihood of the patient’s story being communicated accurately, and improve trust within the doctor/patient relationship.

3. Technologies and strategies that enable patients to have control over who uses their health data and biospecimens, and enable them to learn, who has accessed their health data, which has shown to improve patient autonomy and trust in their providers.

4. Reducing the burden patients currently experience when attempting to access and use their own health information through patient-facing informatics tools, such as more usable patient portals, HIE interfaces, and other aggregation tools.
5. Use of tools to translate technical language and medical abbreviations to lay terms whenever possible to facilitate improved communication and promote health literacy.\textsuperscript{11,12}

6. Using a wide range of technologies, (e.g., web-based portals, telemedicine, apps and APIs, mobile health, and social media) to encourage and enhance patients’ active participation in their health care, which has been shown to improve health outcomes such as medication adherence\textsuperscript{13} and reduced urgent care utilization.\textsuperscript{14}

7. Ongoing and enhanced efforts to fund research that contributes to and advances the design and evaluation of digital technologies that enable patients to manage their own health and that of their families.\textsuperscript{15,16}

8. Patients’ efforts to design, test, and validate new technologies that help them manage their health and the health of their families.\textsuperscript{17}

9. Payment policies and other incentives that promote patient-centered care coordination using evidence-based informatics tools, so that patient needs and preferences are taken into account.\textsuperscript{18}


\textsuperscript{10} De Lusignan, S., Mold, F., Sheikh, A., et al. (2014). Patients’ online access to their electronic health records and linked online services: A systematic interpretative review. \textit{BMJ Open}, 4, e006021


\textsuperscript{13} Lyles, C., Sarkar, U. et al. (2016). Refilling medications through an online patient portal: consistent improvements in adherence across racial/ethnic groups. \textit{Journal of the American Medical Informatics Association}. 2016;23:e28–e33


AMIA Believes:

Assuring the safe use and general safety of health IT is a shared responsibility among oversight bodies, developers, implementers, organizations, hospitals, practices, users, and patients.

Health IT and the practice of clinical informatics play a vital role in identifying more effective medical interventions, preventing errors, improving patient safety, and enabling learning healthcare systems; however, health IT can also introduce new and novel errors and risks to patient safety.

Identifying and mitigating risks introduced by health IT in a coordinated, non-punitive environment, both at the local/organizational and national/systems level, is an essential component for fulfilling the promise of a highly functional health IT ecosystem.

Trained professionals with experience in clinical informatics are essential to design, implement, maintain and evaluate clinical systems to assure safety and quality of care.

Based on these Principles, AMIA Supports:

1. The establishment of a national public/private center, or collaborative, on health IT safety meant to convene, analyze and disseminate information to improve the safety and safe use of health IT.¹

2. The use of standardized reporting mechanisms² and patient safety organizations³ to aggregate, analyze and share information on health IT-related patient safety events across the care continuum.

3. The development of prioritized health IT-related safety measures to ensure (1) that clinicians and patients have a baseline understanding of safe health IT and potential risks; (2) that health IT is properly integrated and used within healthcare organizations to
deliver safe care; and (3) that health IT is part of continuous improvement processes to make care safer and more effective.4

4. Efforts to fund research that contributes to and advances health IT safety, including research that develops new IT to improve safety, as well as evaluates the safety of live health IT systems as used in practice, so that a robust evidence base can inform the total health IT lifecycle and identify ways to remediate risks.

5. Efforts to train and credential health informatics experts at all levels, such as physicians, nurses, pharmacists and researchers, to identify and address health IT safety issues.

6. Regulatory and oversight frameworks that are designed to be proportional to the risk of the activity, and reflective of clinicians’ ability to intervene in the activity being informed by health IT.5

7. Policies, strategies and technical standards that facilitate health IT-related patient safety event reporting by front-line clinicians and patients.6

8. Development and refinement of best practices meant to enable healthcare organizations to address health IT safety within and across organizations, such as ECRI’s Copy & Paste Toolkit7 and ONC’s SAFER Guides.8

9. Health IT developers’ contractual language and implementation decisions that allow users to readily disclose errors, bugs, design issues, and software-related hazards for the benefit of patient safety and scholarship, while also enabling protections for health IT intellectual property.9

10. The application of quality principles and risk management processes – across the health IT lifecycle of design & development, implementation & use, optimization and decommissioning – to improve health IT safety.10

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WORKFORCE & EDUCATION

AMIA Believes:

The digitization of care delivery is transforming the health and research enterprise; the workforce and educational skills needed to optimize this transformation must include both basic informatics literacy for all health professionals and the option to receive more advanced applied informatics training.

Such a workforce will only be realized with financial support for educational professionals, who advance the science of informatics and train the next generation of informatics professionals.

Based on these Principles, AMIA Supports:

1. Efforts to develop and recognize standardized curricula for health informatics training in specific domains. Ideally, such curricula should be overseen by one or more accreditation bodies, where applicable accreditation bodies exist, so that the current and future healthcare delivery and research workforce has the necessary skillset to advance the learning health system.¹²³

2. Educational and training programs that emphasize the transdisciplinary and socio-technical nature of health IT-enabled care through adequate in-the-field training options for more rigorous programs, to ensure the healthcare workforce is exposed to the cultural and role relationships within and across teams.

3. Efforts to develop basic health informatics training and education for baccalaureate, associate and high school students, so they are exposed to health informatics as a discipline earlier in their academic careers.

4. Federal and state-dedicated funding for informatics training, internships, and apprenticeships, so our health and research enterprises will be supported with a competent workforce.⁴⁵

5. Ways to enlarge and sustain advanced formal training for physicians, nurses and other healthcare professionals, such as federal funding for ACGME-accredited Clinical
Informatics training programs and advanced degrees in Nursing Informatics, so anticipated shortfalls in workforce are avoided and clinical settings have the experts they need.  

6. The creation of a designated health informatics Standard Occupational Classification code by the federal government, so accurate employment data can inform public sector decision-making, private sector investment and academic programming.  

7. The creation of a designated informatics “expertise code” for NIH consultant files.

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[http://1.usa.gov/29003at](http://1.usa.gov/29003at)
DATA SHARING IN RESEARCH

AMIA Believes:

1. Data sharing among stakeholders is foundational to: advance scientific discovery; improve benefit / risk assessments; conduct comparative effectiveness research; prevent medical errors; and promote biomedical research rigor, transparency, and reproducibility.

2. Data sharing should preserve and protect patient and consumer privacy and autonomy.

3. The science and application of informatics facilitates and improves knowledge gained through data sharing, and should foster a culture of transparency among patients, consumers, researchers, providers, health care organizations, and the vendors and business associates that handle patient and consumer data.

4. The advantages of data sharing can only be realized with appropriate levels of investment in underlying infrastructure, including tools for data management, human resources for curating shared data, and computing tools for storing and indexing increasingly large and diverse data sets.

Based on these Principles, AMIA Supports:

1. Activities that provide, promote and harmonize robust data sharing infrastructures, including hardware, software and data standards so that data sharing efforts are optimized to achieve their stated goals.

2. The implementation of data standards that can be used for consumer- and patient-generated data, electronic health records, and other clinical health IT that could be useful to informatics researchers to convey summary data, individual participant data and metadata for different types of research to help amplify scientific knowledge while minimizing risks to privacy.

3. Dedicated funding from research sponsors for data curation and donation efforts so there are sufficient incentives to share, collaborate, and advance data sharing capabilities.
4. Institutional rewards for scholars who create and/or contribute to public datasets and software that others find useful so that incentives exist for those who create as well as those who analyze data.4

5. The creation of harmonized regulatory and/or policy frameworks for data sharing, including: data use agreements; data sharing plans; human-subjects reviews and federal, state and local privacy requirements to minimize barriers to share data.5

6. Investment in innovative approaches to data sharing involving a range of technical approaches, including downloading of data and sharing of computational resources that might enable computation over data sets that cannot be shared directly due to regulatory or other concerns.6,7

7. Data sharing across the translational spectrum, from animal model bioinformatics to human health outcome data, to generate breakthroughs in understanding human disease,8 to assess the safety / efficacy of medical products9 and interventions,10 and to improve our ability to digitally detect emerging public health & safety threats.11

8. The incorporation of the FAIR data principles (findable, accessible, interoperable and reusable) to optimize the use of resources and data.12

9. Efforts to develop metrics on the valuation of data curation, including ways to assess the benefits of data sharing and the marginal cost/benefits of curation.

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1 Examples include: BD2K, CTSA, PCORnet, and BioCADDIE (biocaddie.org)
6 Hrynszkiewicz, I., Khodiyar, V., Hufton, A., Sanson, S., “Publishing descriptions of non-public clinical datasets: proposed guidance for researchers, repositories, editors and funding organizations,” Research Integrity and Peer Review. 2016. 1:6
7 Examples include: Yale Open Data Access (YODA; http://yoda.yale.edu/); Clinical Study Data Request (CSDR; http://clinicalstudydatarequest.com); and Vivi (http://www.vivi.org)
8 Examples include: Online Mendelian Inheritance in Man (http://www.omim.org/) and the Model Organism Databases, National Human Genome Research Institute. Available at https://www.genome.gov/10001837/model-organism-databases/
12 “FAIR data principles,” The Future of Research Communications and e-Scholarship. Available at https://www.force11.org/group/fairgroup/fairprinciples
AMIA Believes:

Clinical, research and health information technology (HIT) systems must be able to exchange biomedical, clinical, and health data consistently and reliably using computable formats while preserving the intended meaning and relationships.

Access to and reliable use of these electronic data at scale requires that established, consistent, well-published, and openly available HIT standards be used to specify the formats and values for biomedical, clinical, and health data.

To ensure the consistency and comparability of biomedical and clinical data, HIT standards must have coordinated development, open participation, and transparent governance.

Whenever possible, one canonical specification should be designated as the preferred representation for each biomedical, clinical, and health data standard that are required for defined use-cases related to optimizing health and healthcare.

Testing of HIT systems should test both conformance to the standard and interoperability of the standard to ensure data consistency and reliability across implementations.

Based on these Principles, AMIA Supports:

1. The development and management of HIT standards as a public good, operated in a non-profit, non-proprietary basis, with low barriers to review, reference, or use.

2. HIT standards that leverage existing information technology stacks, such as the Internet Protocol Suite,\(^1\) to greatly expand the functionality of existing information systems, and increase the use of HIT standards by disparate systems.

3. HIT standards that are modular and substitutable, having clear boundaries for use and application, with specifications for automated access, use, and integration with relevant data.

\(^{1}\) Also known as TCP/IP (https://www.ietf.org/)
4. HIT standards that are simple, parsimonious, and include documentation that is complete, comprehensible, readily available, and timely.

5. HIT standards that are fit for purpose within a declared domain, and clearly recognized and identifiable as the preferred standard.²

6. HIT standards that leverage prevailing security practices to protect and preserve privacy and confidentiality.

7. Efforts to recognize and address stakeholder motivations, aims, activities, business models, and information needs in the specification of HIT standards so as to increase the value of their adoption by users and improve ease of implementation.

8. Standards development that incorporates implementation experience and feedback loops from real-world settings to better support an adoption pathway for HIT standards.

9. New modalities of biomedical data, use cases, and information technology that can evolve and mature through implementation experience before canonical specifications can be identified as the standard.

10. Interoperability testing, which tests both the sending of data using a specific standard(s) as well as receipt of data using such standard(s), and tests adherence to Postel’s Principle.³

11. Adequate funding for the development, management and maintenance of HIT standards, and the SDOs that create them, due to the enormous positive impact on society HIT interoperability can have.

² This criterion implies being comprehensive within a declared domain of information, purpose and context, and generating verifiable content, preserving provenance, and computer interpretable.

AMIA Believes:

The purpose of measurement is to improve the quality and safety of care, identify areas for care delivery improvement, and maximize value for patients, for populations, and for the US healthcare system as a whole.

Electronic quality measure concepts should be based on data available in EHRs, gathered in the process of care, and other health IT to which clinicians have access. Further, data used to compile quality measures should be drawn from where it is routinely collected, and able to be queried in its native environment to generate quality measures in a computable and semantically interoperable fashion.

It is not enough that a measure be deemed clinically appropriate for endorsement; the measure should also be demonstrably implementable in the clinical setting, balancing value with provider time required during visits, so that the measure can be collected, reported, and submitted automatically.

Consensus measurement governance and processes must include informatics professionals who are uniquely qualified to ensure that quality measures are clinically meaningful, implementable in an electronic environment, and scalable to address different patient population needs.

Based on these Principles, AMIA Supports:

1. Development of evidence-based quality measures that are aligned with existing data in the care record and can be captured through routine practice without impairing patient-provider communication.

2. Development of evidence-based quality measures that are clinically relevant to providers and meaningful to patients.  

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4 In a survey reported in Health Affairs, only 27 percent of responding physicians believed that current measures were moderately or very representative of the quality of care they provided. The report also stated that US physician practices are spending $14.5 billion dollars annually – on average about $40,000 per physician to report quality measures that may not have a large impact on health. (Casalino LP, Gans D, Weber R, Cea M, Tuchovskyy A, Bishop TF, Miranda Y, Frankel BA, Ziehler KB, Wong MM, Evenson TB. US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures. Health Aff (Millwood). 2016 Mar; 35:401-6.)
3. Clinicians’ ability to select among consensus measures that they feel best represent their specialty and patient populations.

4. Evidence-based quality measures that support individualized care, and are flexible enough to facilitate reporting of unique patient experiences as well as patient populations.\(^5\)\(^6\)\(^7\)

5. A measure development process that is transparent, consistent, inclusive, and includes a parallel quality assurance mechanism to ensure all measures developed through the process are aligned with a holistic strategy.

6. Efforts to simplify quality measure development and streamline quality measure approval processes, including a firm set of selection criteria and strict endorsement processes.\(^8\)

7. Efforts to bring measure developers together with health IT developers, the clinical community, and informatics professionals so that implementation guidelines and best practices accompany quality measures.

8. Efforts to test both the accuracy of the measure calculation, and the feasibility of the data collection requirements, impact on patient-provider communication during visits, to improve the ability to consistently implement the measures.

9. Efforts to leverage quality measure data in ways that are communicated back to the clinician and patients.

10. Programs and policies that increase and prioritize the development of outcome measures, to enable a shift away from process measures.

11. Gradual implementation of reporting requirements to allow for alignment with workflow processes and time requirements.

12. Rigorous ongoing monitoring of effectiveness of measures, so that measures remain relevant to practice and patients.\(^9\)

13. The creation of a “safe harbor” status for organizations that utilize their own vetted measurement systems, to advance performance measure development.\(^10\)

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\(^8\) See the NCQA: [http://www.ncqa.org/Portals/0/HEDISQM/Measure_Development.pdf](http://www.ncqa.org/Portals/0/HEDISQM/Measure_Development.pdf)
