AMIA PUBLIC POLICY PRINCIPLES AND POLICY POSITIONS

2016 – 2017 Priorities

CONTENTS

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:

AMIA Policy Principles

Policies, programs, research and care delivery should seek to empower patients through access to, and control of, their personal health information.

Health informatics is key to enabling delivery of patient-centered care.

Patients must play a vital role in the development of public policy as well as publicly-funded programs & research.

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,[1,2] biomedical discovery,[3] 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,[4] lead to improved self-care,[5] increase the likelihood of the patient's story being communicated accurately,[6] and improve trust within the doctor/patient relationship.[7]

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. [8,9]

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.[10]

5. Use of tools to translate technical language and medical abbreviations to lay terms whenever possible to facilitate improved communication and promote health literacy.[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[13] and reduced urgent care utilization.[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.[15, 16]

8. Patients' efforts to design, test, and validate new technologies that help them manage their health and the health of their families.[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.[18]

[1] Klein D., Fix ., et al. (2015). Use of the Blue Button Online Tool for Sharing Health Information: Qualitative Interviews With Patients and Providers. *Journal of Medical Internet Research*. 2015 Aug; 17(8): e199.

[2] Mohsen, M., Aziz, H. (2015). The Blue Button Project: Engaging Patients in Healthcare by a Click of a Button *Perspectives in Health Information Management*. 2015 Spring; 12(Spring); 1d.

[3] Chisholm, R., Denny J., et al. (2015) Opportunities and Challenges Related to the use of Electronic Health Records Data for Research. *National Institutes of Health Precision Medicine Workshop (Invited White Paper)*. 2015 Feb.

[4] Esch T., Mejilla R., et al. (2016). Engaging patients through open notes: an evaluation using mixed methods. *BMJ Open* 2016;6:e010034.

[5] Wright E., Darer J., et al. (2015). Sharing Physician Notes Through an Electronic Portal is Associated With Improved Medication Adherence: Quasi-Experimental Study. *Journal of Medical Internet Research,* 17(10)e:226

[6] Varpio, L., Rashotte, J., et al. (2015). The EHR and building the patient's story: A qualitative investigation of how EHR use obstructs a vital clinical activity. *International Journal of Medical Informatics, 84*(12), 1019-1028

[7] Bell S., Mejilla R., Anselmo M., et al. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities, and the patient-doctor relationship. *BMJ Qual Saf* 2016

[8] Caine K., Hanania R. (2013) "Patients want granular privacy control over health information in electronic medical records." *Journal of the American Medical Informatics Association*. 2013;20:7–15.

[9] Weinfurt, K., Bollinger, J., et al. "Patients' views concerning research on medical practices: Implications for consent." *AJOB Empirical Bioethics*. 2016:7(2)

[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. *BMJ Open, 4,* e006021

[11] Ratanawongsa N, Barton J et al. Computer use, language, and literacy in safety net clinic communication. *Journal of the American Medical Informatics Association*. 2016; pii: ocw062. doi: 10.1093/jamia/ocw062.

[12] Brach C, Keller D. Ten attributes of health literate health care organizations. June 2012. Institute of Medicine. https://nam.edu/wp-content/uploads/2015/06/BPH_Ten_HLit_Attributes.pdf.

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

[14] Shimada SL, Hogan TP, et al. (2013) Patient-provider secure messaging in VA: variations in adoption and association with urgent care utilization. *Med Care. 2013 Mar; 51(3 Suppl 1):S21-8.*

[15] Parmanto B, Pramana G, et al. Development of mHealth system for supporting self-management and remote consultation of skincare. *BMC Medical Informatics and Decision Making*. 2015;15:114.

[16] Piette JD, List J, Rana GK, Townsend W, Striplin D, Heisler M. Mobile health devices as tools for worldwide cardiovascular risk reduction and disease management. Circulation. 2015;132(21):2012-2017.

[17] Lee JM, Hirschfeld E, Wedding J. A patient-designed do-it-yourself mobile technology system for diabetes: promise and challenges for a new era in medicine. *JAMA*. 2016:315(44):1447-1448.

[18] Demiris, G., Kneale, L., Informatics Systems and Tools to Facilitate Patient-centered Care Coordination. *Yearbook of Medical Informatics*. 2015; 10(1): 15–21.

HEALTH IT SAFETY

AMIA Believes:

AMIA Policy Principles

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 mechanisms[2] and patient safety organizations[3] 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 Toolkit[7] 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]

---

[1] Office of the National Coordinator for Health IT, "Health IT Safety Center Roadmap," RTI International. July 2015. Available: http://www.healthitsafety.org/

[2] Agency for Healthcare Research and Quality, "Common Formats," Available: https://pso.ahrq.gov/common

[3] Agency for Healthcare Research and Quality, "Patient Safety Organization (PSO) Program," Available: https://pso.ahrq.gov

[4] National Quality Forum, "Identification and Prioritization of Health IT Patient Safety Measures," Feb. 2016. Available: http://bit.ly/297AWDV

[5] Bipartisan Policy Center Health Innovation Initiative, "An Oversight Framework for Assuring Patient Safety in Health Information Technology," Feb. 2013. Available: http://bit.ly/297Ardb

[6] Huerta T., Walker C., Murray K., et al "Patient Safety Errors: Leveraging Health Information Technology to Facilitate Patient Reporting." *Journal for Healthcare Quality*, 2016 Jan-Feb; 38(1): 17-23

[7] ECRI Partnership for Health IT Patient Safety, "Health IT Safe Practices: Toolkit for the Safe Use of Copy and Paste," ECRI Institute, Feb. 2016. Available: http://bit.ly/297z7qo

[8] Sittig, D.; Ash, J.; Singh, H. "ONC Issues Guides for SAFER EHRs" *Journal of AHIMA* 85, no.4 (April 2014): 50-52.

[9] Goodman, K., Berner, E., Dente, M., et al "Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force," *Journal of the American Medical Informatics Association,* 2011 18: 77-81

[10] "AAMI Launches Health IT Standards Initiative," AAMI. Aug. 2015. Available: http://bit.ly/297AHbY

WORKFORCE & EDUCATION

AMIA Believes:

AMIA Policy Principles

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. [1,2,3]

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. [4,5]

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. [6,7]

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.[8]

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

[1] Safran C, Shabot MM, Munger BS, Holmes JH, Steen EB, Lumpkin JR, et al. Program Requirements for Fellowship Education in the Subspecialty of Clinical Informatics. *Journal of the American Medical Informatics Association*. 2009;16(2):158-66.

[2] Gardner RM, Overhage JM, Steen EB, Munger BS, Holmes JH, Williamson JJ, et al. Core Content for the Subspecialty of Clinical Informatics. *Journal of the American Medical Informatics Association*. 2009;16(2):153-7.

[3] Silverman H, Lehmann CU, Munger B. Milestones: Critical Elements in Clinical Informatics Fellowship Programs. *Journal of Applied Clinical Informatics*. 2016;7(1):177-90.

[4] Kannry J, Sengstack P, Thyvalikakath TP, Poikonen J, Middleton B, Payne T, et al. The Chief Clinical Informatics Officer (CCIO): AMIA Task Force Report on CCIO Knowledge, Education, and Skillset Requirements. *Journal of Applied Clinical Informatics*. 2016;7(1):143-76

[5] Kannry J, Fridsma D. The Chief Clinical Informatics Officer (CCIO). *Journal of the American Medical Informatics Association*. 2016;23(2):435.

[6] Lehmann CU, Longhurst CA, Hersh W, Mohan V, Levy BP, Embi PJ, et al. Clinical Informatics Fellowship Programs: In Search of a Viable Financial Model: An open letter to the Centers for Medicare and Medicaid Services. *Journal of Applied Clinical Informatics*. 2015;6(2):267-70.

[7] Detmer DE, Munger BS, Lehmann CU. Clinical informatics board certification: history, current status, and predicted impact on the clinical informatics workforce. *Journal of Applied Clinical Informatics*. 2010;1(1):11-8.

[8] Bureau of Labor Statistics, U.S. Department of Labor, "Standard Occupational Classification System" http://1.usa.gov/29003at

DATA SHARING IN RESEARCH

AMIA Believes:

<div style="vertical-align: middle">

AMIA Policy Principles

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.

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

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.

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.

</div>

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.[1]

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.[2]

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.[3]

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 products[9] 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.

---

[1] Examples include: BD2K, CTSA, PCORnet, and BioCADDIE (biocaddie.org)

[2] National Academy of Medicine (formerly Institute of Medicine) "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk," Jan. 2015 http://bit.ly/1Vwtnbi

[3] Borne, P., Lorsch, J., Green, E., "Perspective: Sustaining the big-data ecosystem," *Nature*. November 2015. 527, S16–S17

[4] Piwowar, H., Vision, T., "Data reuse and the open data citation advantage," *Peer J*. 2013. 1:e175

[5] Taichman, D., Backus, J., Baethge, C., et al. "Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors," *Annals of Internal Medicine*. 2016. doi:10.7326/M15-2928

[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 Vivli (http://www.vivli.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/

[9] National medical device evaluation system Planning Board Report, "Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System," Duke-Margolis Center for Health Policy. April 2016. Available at http://bit.ly/29aJP1y

[10] Office of the National Coordinator for Health IT, "Health IT Safety Center Roadmap," RTI International. July 2015. Available: http://www.healthitsafety.org/

[11] Velsko, S., Bates, T. "A Conceptual Architecture for National Biosurveillance: Moving Beyond Situational Awareness to Enable Digital Detection of Emerging Threats." *Health Security*. 2016 May-Jun; 14(3):189-201.

[12] "FAIR data principles," The Future of Research Communications and e-Scholarship. Available at https://www.force11.org/group/fairgroup/fairprinciples