AMIA PUBLIC POLICY PRINCIPLES AND POLICY POSITIONS

2024 – 2029 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 efficacy; 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 nine initial pillars as core to Health Informatics Policy, including: Patient Empowerment, Health IT Safety, Workforce and Education, Data Sharing in Research, Health IT Data Standards & Interoperability, Informatics-Driven Quality Measurement, Population & Public Health, Health Data Privacy, and AI Principles.

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 result from these Principles, and they are supported by 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 most important at this time. 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

Individuals' personal health information is central to healthcare and biomedical research. These Patient Empowerment Principles and Positions highlight the central role of the individual in the generation of and management of their health care and research data with biomedical informatics and consumer technologies, as individuals' expectations grow for transparency and trust in how technology can enable and empower care and research experiences.

AMIA Believes:

AMIA Policy Principles

Policies, programs, research and care delivery should empower individuals to access and control their personal health information.

Effective integration and interoperability of rich contextual data about patients and generated by patients will lead to better health outcomes, including social, behavioral, genomic, environmental, and geographic health data.

Biomedical informatics and digital inclusion are key to enabling delivery of person at the center care and research. Digital literacy training is foundational to support and promote the use of person-directed health information technologies.

Digital inclusion, as defined by the National Digital Inclusion Alliance[1] and supported by the Infrastructure Investment and Jobs Act,[2] refers to the activities necessary to ensure that all individuals and communities have access to and the digital literacy to use information and communications technology.[1]

Individuals, as patients and research participants, must be

engaged and supported to inform the co-development and creation of public policy and publicly funded programs & research that support the safe and trusted use of person-directed health information technologies.[3]

Transparency around the development of health technologies, including rapid advances in artificial intelligence and the use of its data are critical for trust and accountability.

Documentation burden should not be shifted to the person, when efforts are introduced to mitigate health professional burden.[4]

Based on these Principles, AMIA Supports:

1. Efforts that enable individuals to access and transmit all electronic data contained in their electronic health record[5], rather than a limited or pre-defined set of data, to improve availability of data for care delivery,[6] biomedical discovery[7] and in support of individuals' health and wellness.[8]

2. Technology-enabled approaches that promote individual's engagement in their health records, including efforts such as Open Notes encouraging patients to review and contribute directly to their record, have been shown to a) improve their understanding of their own health information,[9] b) lead to improved self-care,[10,11] c) increase the likelihood of the patient's story being communicated accurately,[12] and d) improve trust within the doctor/patient relationship.[13]

3. Technologies and strategies that enable individuals to have control over who accesses and uses their health data and biospecimens and learn who has accessed their health data, improve patient autonomy and trust in their providers.[14,15]

4. Frameworks are needed to increase levels of digital inclusion and digital equity, and effectively measure outcomes. These efforts include access to technology and underlying infrastructure, digital literacy, and the development of[12] skills needed for both patients and providers, to enhance outcomes of technology use and integration.[11,16,17]

5. Minimizing the burden individuals experience when attempting to access and use their own health information through patient-facing informatics tools, such as usable and accessible patient portals, Health Information/TEFCA portals, and other aggregation tools. Policies must create a balance, curtailing any shift in

burden from health professionals to patients and consider the patient impact when developing documentation burden mitigating solutions.[18,19,20]

6. Use of tools to translate technical language and medical abbreviations to lay terms to facilitate improved communication and promote health literacy.[21,22]

7. Using a wide range of technologies, (e.g., web-based portals, telemedicine, apps and APIs, mobile health, wearables and social media) to encourage and enhance individuals' active participation in their health care,[23,24] and improve health outcomes such as medication adherence[13] and reduced urgent care utilization.[25]

8. Ongoing and enhanced efforts to fund patient centered outcomes research[26] 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.[27,28]

9. Including patients in the design, testing, and validation of new technologies that help them manage their health and the health of their families.[29,30]

10. Advancing transparent payment policies and initiatives that promote person at the center care coordination augmented by a wide range of technologies that accommodate patient needs and preferences,[31,32] especially efforts to simplify and reduce the impact of prior authorization on the patient and health professional.[33]

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HEALTH INFORMATION TECHNOLOGY SAFETY

Biomedical informatics is broader than simply the technology used to digitally manage records of health and wellness. It includes operational structures, processes and practices, shared meanings, people, culture, and the environment surrounding these elements. These Principles and Positions describe factors that contribute to health IT safety and actions necessary to prevent patient harm through health IT.

AMIA Believes:

AMIA Policy Principles

Design, implementation, maintenance, and evaluation of health information technology (HIT) can only be credibly carried out by multidisciplinary teams led by trained biomedical informatics professionals.

Assuring the safe use and general safety of HIT is a shared responsibility amongst oversight (government and non-government) bodies, developers, implementers, organizations, health systems, practices, users, and patients.

HIT 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, HIT can also introduce new and novel errors, burden, and risks to patient safety.

Identifying and mitigating risks introduced by HIT in a coordinated, collaborative, and non-punitive environment, both at the local/organizational and national/systems level, are essential components for fulfilling the promise of a highly functional HIT ecosystem.

Sharing information about harm (intended or not) by HIT enables system improvement. Safe and supervised spaces are required to allow sharing of cases and information about where and when HIT has caused harm to patients and clinicians, or others, regardless of whether the harm is related to the

technology, people, or operational processes, alone or in combination.

Based on these Principles, AMIA Supports:

1. The establishment of a national HIT safety public/private center, or collaborative, designed to convene, analyze and disseminate information to improve the safety and safe use of HIT.[1, 2]

2. The use of standardized reporting mechanisms[3] and patient safety organizations[4] to aggregate, analyze and share information on HIT-related patient safety events across heath cares settings[5] and the care continuum.

3. The development of prioritized HIT-related safety measures to ensure (1) that clinicians and patients have a baseline understanding of safe HIT and potential risks; (2) that HIT is properly integrated and used within healthcare organizations to deliver safe care; and (3) that HIT is part of continuous improvement processes to make care safer and more effective.[6,7]

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

5. Efforts to train and credential health informatics experts at all levels, such as physicians, advanced practice professionals, nurses, professional clinical support staff (e.g., NPs and PAs), allied health staff (e.g., pharmacy, lab, radiology, therapies) and researchers, to identify and address HIT 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 HIT.[8]

7. Policies, strategies and technical standards that facilitate HIT-related patient safety event reporting by front-line clinicians, allied health staff, and patients.[9]

8. Development and refinement of best practices meant to enable healthcare organizations to address HIT safety within and across organizations, such as ECRI's Copy & Paste Toolkit[10] and ONC's SAFER Guides.[11,12]

9. Contracts and practices that promote safety, disclosure of errors, bugs, design issues, and software-related hazards, while permitting protection of intellectual property.[13,14]

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.[15]

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WORKFORCE & EDUCATION

A well-trained and skilled biomedical informatics workforce committed to lifelong learning and qualified to make data-driven, evidence-based, systems-level improvements in care delivery using health IT, is essential to the success of healthcare systems and research enterprises. These Principles and Positions articulate the importance of well-funded education and training programs for biomedical informatics professionals, and identify key policy levers necessary to recruit, retain, and integrate such professionals within current and future workforce structures.

AMIA Believes:

AMIA Policy Principles

Digitization of healthcare data has transformed the health and research enterprise. Building and sustaining the workforce needed to accelerate healthcare transformation through digital data requires education and skills. This includes basic biomedical informatics literacy and competencies for all levels of healthcare professionals, as well as access to both on-going and advanced applied biomedical informatics training.

A digitally competent healthcare workforce can only be achieved and sustained with institutional recognition and prioritization of relevant biomedical informatics training for those who work in healthcare-related fields. This requires financial support for educational professionals who teach, role model, and advance the discovery of new knowledge as they train the next generation of biomedical informatics professionals.

Based on these Principles, AMIA Supports:

1. Efforts to develop and recognize standardized curricula for biomedical informatics training. Ideally, such curricula should be governed by one or more applicable accreditation bodies, so that the healthcare delivery and research workforce have the necessary skills to continuously advance learning health systems. [1,2,3,4]

2. Educational and training programs that emphasize the multidisciplinary and socio-technical nature of health IT-enabled collaborative and coordinated care through supervised training experiences in clinical care settings, including exposure to the

cultural and role relationships within and across care delivery teams.[5]

3. Efforts to develop basic biomedical informatics training and education for baccalaureate, associate degree, and high school students, to facilitate exposure to biomedical informatics as a discipline earlier in their academic careers.[6]

4. Efforts to develop, deliver and evaluate basic biomedical informatics competencies that all undergraduate, graduate and postgraduate health professionals should have to deliver care individually and in teams, as well as to engage in scholarly work (research, quality and performance improvement) as appropriate.[7]

5. Federal and state funding for biomedical informatics training, internships, and apprenticeships, including funding for program effectiveness and ongoing improvement, so our health and research enterprises will be supported with a competent workforce.[8,9]

6. 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. [10,11]

7. The creation of a designated biomedical 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.[12]

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DATA SHARING IN RESEARCH

The continued digitalization of healthcare data fuels data-driven biomedical and clinical research. These Principles and Positions articulate the role biomedical informatics plays in data sharing, and describes the cultural dynamics, institutional support systems, and policy levers necessary to optimize and sustain ongoing and evolving data sharing practices that support biomedical informatics and clinical research.

AMIA Believes:

AMIA Policy Principles	
	Data sharing among stakeholders is critical to advance scientific discovery; improve benefit / risk assessments; conduct comparative effectiveness research; improve patient safety; and promote biomedical research rigor, transparency, and reproducibility.
	Data sharing must preserve and protect patient and consumer privacy and autonomy.
	The science and application of biomedical informatics facilitates and improves knowledge gained through data sharing and should foster a culture of trust and 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, collaborations that set data sharing standards, tools that manage, store, and index large and diverse data sets, as well as human resources that curate and secure shared data.

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.[1,2,3]

2. The implementation of data standards that can be used for consumer- and patient-

generated data, electronic health records, and other data that could be useful to biomedical informatics researchers to convey summary data in a usable format, individual participant data and metadata for different types of research to help amplify scientific knowledge while minimizing risks to privacy.[4,5,6]

3. Dedicated and consistent funding from research sponsors for data curation and sharing efforts so there are sufficient incentives to share, collaborate, and advance data sharing capabilities.[7,8,9]

4. Institutional rewards and recognition for those who create and/or contribute to public datasets and software that are useful so that incentives exist for those who create as well as those who analyze data.[10,11]

5. The creation of harmonized regulatory and/or policy frameworks for data sharing, including data use agreements; data sharing plans; consumer/patient input, engagement, and evaluation; human-subjects reviews and federal, state and local privacy requirements to minimize barriers to sharing data.[12,13]

6. Investment in innovative approaches to data sharing involving a range of technical approaches, including sharing of computational resources that might enable computation over data sets that cannot be shared directly due to regulatory or other concerns.[14,15,16,17]

7. Data sharing across the translational spectrum, from animal model bioinformatics to human health outcome data.[18,19]

8. The incorporation of the FAIR data principles (findable, accessible, interoperable and reusable) to optimize the use of resources and data.[20]

9. Efforts to develop evaluation frameworks that assess the value of data sharing and curation.

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HIT DATA STANDARDS & INTEROPERABILITY

Technical standards enable disparate systems to communicate and are prerequisites for our health information technology (HIT) ecosystems to interoperate. AMIA's Principles and Positions describe the desired characteristics of health IT standards for care and research, and articulate the importance of governance, testing, and multistakeholder standards development.

AMIA Believes:

AMIA Policy Principles

Clinical, research and HIT systems must be able to exchange biomedical, clinical, and health data consistently and reliably using computable, and where appropriate, standardized formats while preserving the intended meaning and inter-relationships.

Access to and reliable use of digital healthcare data at scale requires that established, consistent, published, and openly available HIT standards be used to specify the formats and characteristics (such as data types, ranges, etc.) for biomedical, clinical, and health data.

To ensure consistency and comparability of biomedical and clinical data, HIT standards must require coordinated and collaborative development through official announcements, open public comment periods, and published meeting notes.

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

Testing of HIT systems should test both conformance to, and interoperability of standards in real world environments to ensure data consistency and reliability across a diverse spectrum of implementations and use cases.

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.[1]

2. HIT standards that leverage existing information technology stacks, such as the Internet Protocol Suite[2,3] and the Trusted Exchange Framework and Common Agreement (TEFCA)[4] that 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 extensible, expandable boundaries for use and application, with specifications for automated access, use, and integration with relevant data.

4. HIT standards that are simple, parsimonious, and include documentation that is comprehensive, comprehensible, readily available, actionable, and timely.

5. HIT standards that are fit for purpose within a declared domain, and clearly recognized and identifiable as the preferred standard. [5,6]

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

7. Efforts to recognize and address stakeholder motivations, aims, activities, business models, and information needs in the specification of HIT standards 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. Interdisciplinary collaboration on potential standards for 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.[7,8]

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.

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BIOMEDICAL INFORMATICS-DRIVEN QUALITY MEASUREMENT

The ability to accurately and consistently measure quality and safety of care delivery underlies our national healthcare system. These Principles and Positions describe the characteristics of quality measures in a digital healthcare data environment, the governance processes needed to develop such measures, and the public policies needed to ensure that modern quality measures are meaningful to all stakeholders.

AMIA Believes:

AMIA Policy Principles

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

Digital quality measures should emphasize the use of data available in EHRs, gathered during the delivery of care and maintenance of health. Data from other health IT systems may also be required to augment EHR data. Further, data used to compile quality measures must be queried in its native environment in a computable and semantically interoperable fashion.

Endorsement of quality measures should only be granted when they are deemed both clinically appropriate and demonstrably implementable in the context of healthcare delivery and health maintenance. Operationally, the measure is collected, reported, and submitted automatically.

Consensus quality measurement governance and processes must include biomedical informatics professionals who are qualified to ensure that quality measures are clinically meaningful, efficiently integrated in workflow, implementable in digital environments, and both scalable and sufficiently transferable to address different patient population needs.

The use of data for quality measurement carries the risk of bias.

While the use of Artificial Intelligence (AI) for Clinical Decision Support (CDS) from available data offers unique promise, its application in healthcare also poses complex challenges. Therefore, data used for evolving types of quality measurement must address human-centered values including fairness, transparency and explainability, interpretability, robustness, security and safety, accountability.

Secondary use of real-world data (RWD) gathered or documented during routine healthcare and health maintenance interactions, requires additional quality measures designed to evaluate its fitness for purpose to provide real-world evidence (RWE) that advances research, supports healthcare decision-making and innovation, and informs public policy.

Additional quality measures should be designed and implemented in ways that do not increase the burden on health care professionals.

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[1, 2, 3, 4]

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 population-level data.[5,6,7,8]

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 defined set of selection criteria and strict endorsement processes.[9, 10]

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 proposed 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 measure implementation.

9. Efforts to leverage quality measure data in ways that are communicated back to clinicians 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.[11]

13. The creation of a "safe harbor" status for organizations that utilize their own vetted measurement systems, to advance performance measure development.[12]

14. Healthcare systems support for biomedical informatics professionals in the governance of healthcare quality.

15. Efforts to encourage collaboration of healthcare system IT leadership with physician, nursing, and pharmacy informatics professionals.

16. Health care organizations, developers, adopt additional tools and measures, such as data cards, to ensure sufficient information is available to downstream AI application developers and deployers to understand context, potential limitations, and biases.

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HEALTH DATA PRIVACY

Note: AMIA defines "Health Data" as data collected about an individual – including genetic, phenotypical, physiological, and behavioral data – which provide, or have the potential to provide, information about the physical or mental state of the individual.

The volume, variety, and velocity of health data are rapidly growing across care delivery, research, community, and commercial settings. These Principles and Positions reflect a set of beliefs and actions necessary to support individual privacy within the context of health informatics policy.

These Principles and Positions apply wherever and whenever health data exist, including within contexts of health care delivery, clinical research, public health, social/community services, and consumer applications.

AMIA Believes:

AMIA Policy Principles

Health data must be protected to reduce the risks of harm to individuals.

Individuals may benefit themselves and others when they share health data for care and research.

The threat of communicable risk, contaminant risk, and other threats to public health necessitates broad access to health data with severe penalties for misuse.

An individual's privacy protections must be consistently maintained, and their privacy preferences respected across clinical, research, community services, and commercial use of their health data.

Informed consent requires clearly worded, understandable explanations of how an individual's health data will be used and the circumstances in which it will be disclosed; a commercial application Terms of Service agreement is not equivalent to, nor a substitute for, informed consent.

Health data must always be collected, managed, and shared in ways that minimize the risk of re-identification of individuals after de-identification.

Health data privacy should not be misconstrued as a justification to avoid or inhibit processes that promote interoperability, data sharing, especially in moments of health emergencies or threats to public safety.

Based on these Principles, AMIA Supports:

1. The regular review and harmonization of federal, state, and tribal privacy policy as technology and society evolve, especially given the expanding use of artificial intelligence (AI) and increasing capacity for data aggregation from diverse sources.

2. Federal privacy policy that lays a foundation for (1) individual data rights and protections; (2) obligations and custodial duties for data owners, managers, and users; and (3) data use prohibitions across jurisdictional and geographic boundaries, while also establishing a process for jurisdictions to address local needs and norms.[1]

3. Federal protections from harassment, targeting, unwanted marketing, bias, discrimination, stigma, and exploitation resulting from use, disclosure, or reidentification of health data.

4. Uniformity of health data access policy, empowering individuals to have complete access to their health data, in machine- and human-readable formats, regardless of covered entity, business associate, or other commercial status.[2]

5. Transparency in how an individual's health data are used or disclosed once collected or generated through clear, easily accessible, and readable explanation of permitted uses.

6. Permissions or consents for data use and disclosure that are accurate, granular, timely, presented in formats that support accessibility by all, understandable across target education levels, revocable, and that are collected from individuals without duress or misleading statements.

7. Development of data standards to support privacy policy, such as through tagging (e.g. Security Labels) and metadata (e.g. provenance).[4]

8. Explicit accommodation for data access, aggregation, and sharing for purposes of public health.[5,6,7]

9. Computable audit trails and accounting of disclosures so individuals can determine who accessed their data, when, and for which purposes.

10. Security systems and controls that protect data in transit and at rest, to prevent unintended access.

11. Authentication of individuals and entities and verification of authorization to receive health data before data are shared.

12. Adequate investigation and enforcement of privacy laws, with consequential penalties for individuals and businesses that violate laws and regulations, and with individual redress for harm.

13. Policies that provide individuals the opportunity to securely dispose of, or transmit or download their health data in the event of a transfer of ownership or in the case of a company ending or selling its business.[8]

14. Policies that confer health data protections to non-health data (such as geolocation), when non-health data are applied to represent an individual's health and wellness, or when such data are used for purposes of health care delivery, medical research or public health.

15. Ongoing funding for research to develop tools and strategies necessary to minimize misuse and inappropriate disclosure of data, increase data privacy and security, and promote data literacy.

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[3]A security label is a concept attached to a resource or bundle that provides specific security metadata about the information it is fixed to. See more at: https://www.hl7.org/fhir/security-labels.html (Accessed August 24, 2024).

[4] Provenance of data is a record that describes entities and processes involved in producing and delivering or otherwise influencing that data. Provenance provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility. Provenance assertions are a form of contextual metadata and can themselves become important records with their own provenance. See more at: https://www.hl7.org/fhir/provenance.html (Accessed August 24, 2024).

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POPULATION & PUBLIC HEALTH

Healthcare has traditionally focused on the interplay between physiological factors (biological/genetic/exposure to disease or injury) and the health of both individuals and populations. It is now well understood that health is also affected by numerous societal factors including geographical and social determinants of health. There is a critical need to understand the interplay of the complex factors contributing to both health and efficacy of the healthcare ecosystem. This requires careful collection and analysis of data generated from it at the individual, community, population, and systems levels.

These Principles and Positions are meant to articulate the role of biomedical informatics in better understanding the health of populations and facilitating the coordination of traditional care delivery with public health to improve both patient and population-level health outcomes.

AMIA Believes:

AMIA Policy Principles

Everyone should have an equitable opportunity to live a healthy/healthier life, regardless of who they are, where they live, or other socioeconomic circumstances.

The activities of medical, social services, and public health entities be coordinated as much as possible to collaborate for the benefit of everyone.

All U.S. health system stakeholders be accountable for assuring equitable access to appropriate care and preventive services to enable a healthy life for both individuals and communities.

Funding and investment for health care and public health should consider the value of preventive and community-based services to support the health of both individuals and populations.

Continued research on the impact of social determinants of health and other factors that influence health status, care delivery and outcomes should integrate data generated in the course of routine interactions with the healthcare system as well as that generated by a public healthcare system that is data-driven and standards-based.

Based on these Principles, AMIA Supports:

1. Better integration, interoperability, and bi-directional sharing of data, information, and knowledge across care delivery, public health agencies, and community-based organizations to inform policy, drive prevention and disease management efforts, and support community resource information sharing. See AMIA Public Policy Principles: HIT Data Standards and Interoperability and Data Sharing in Research.

2. Work to develop nationally scalable, multi-jurisdictional approaches to common public health workflows (e.g., electronic case reporting) for broad dissemination.[1,2]

3. A research agenda focused on developing real-time public health-primary care information loops; improving strategies to engage individuals to assess and promote health (e.g., mobile or virtual technologies); and developing tools to assess social determinants of, and other factors that influence, health.[3,4,5]

4. Development of more sophisticated approaches for protecting individual's confidentially while implementing strategies to improve population health outcomes.

5. Investment in public health informatics workforce training to build competencies and capacity at every level where information is generated, managed, and used for population health.[6,7]

6. The establishment and sustainability of Centers of Excellence for public health informatics to serve as models of best practice for the nation.[8,9]

7. Dedicated funding for training of public health informatics professionals analogous to NIH funding to ensure the continued evolution of the field.[10,11,12]

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ARTIFICIAL INTELLIGENCE PRINCIPLES FOR HEALTHCARE

Artificial Intelligence (AI) refers to an array of computer technologies such as machine learning, deep learning, natural language processing, generative artificial intelligence and other mathematical and statistical techniques that seek to emulate human intelligence, e.g., "thinking", in order to address highly complex problems, often involving vast quantities of data and information.

In healthcare, AI systems are generally intended to lead to new knowledge, make recommendations or trigger actions via the development of complex algorithms, or processes, that analyze data, often in real or near-real-time, and can sometimes adapt to changes over time. Such systems have the potential to advance medical knowledge and make healthcare safer, more effective, less costly, and even more equitable. There are, however, well documented risks associated with all aspects of the design, deployment, and maintenance of AI systems, particularly with respect to the potential for bias in many forms, including algorithmic bias.

As growing numbers of AI systems are deployed in healthcare, the need for ethical principles and governance has become increasingly urgent so that biomedical informaticians can assure that AI in healthcare is developed with appropriate high-quality data; is introduced judiciously, in the appropriate environments; is used for impactful and meaningful purposes; with appropriate training and maintenance and in accordance with core principles that ensure respect, safety and equity for patients, providers, institutions, and society.

AMIA Believes:

Due diligence is required to address the risk of bias and safety in the use of AI in healthcare, which includes:

- A set of core principles that govern all aspects of design, development, testing, deployment and maintenance of biomedical AI systems, products and services as support tools intended for use in healthcare, as well as in more consumer-oriented health and wellness applications.
- Organizations that deploy or develop AI systems for healthcare be governed by a set of principles intended to assure that issues related to the context and purpose of use, maintenance over time, and other implementation issues are addressed.
- Development and deployment of AI systems in healthcare should proactively seek to mitigate the potential unintended socio-cultural impact of such systems with particular emphasis on education, research, and the impact on vulnerable populations,

including groups that have been economically/socially marginalized.

- The biomedical informatics community collaborates to create guidelines for implementation of the principles outlined herein that offer appropriate mechanisms, and where appropriate public and private funding, to assess the degree to which AI systems achieve their purpose, with particular emphasis on principles that prioritize safety, trustworthiness, and equity.

Based on these Principles, AMIA Supports:

AI Systems Principles
1. Autonomy – AI must protect the autonomy of all people and treat them with courtesy and respect including facilitating informed consent.
2. Beneficence – AI must be helpful to people modeled after compassionate, kind, and considerate human behavior.
3. Non-maleficence – AI shall "do no harm" by avoiding, preventing, and minimizing harm or damage to any stakeholder.
4. Justice – AI includes equity for people in representation and access to AI, its data, and its benefits. AI must support social justice.
5. Explainability – Scope, proper application, and limitations of AI must be understandable and provided in context appropriate language.
6. Interpretability – Plausible reasoning for decisions or advice in accessible language must be provided.
7. Fairness – AI must be free of bias and must be non-discriminatory.
8. Dependability – AI must be robust, safe, secure, and resilient. Failure must not leave any system in an unsafe or insecure state.
9. Auditability – AI must provide and preserve a performance "audit trail" including internal changes, model state, input variables, and output for any system decision or recommendation.
10. Knowledge Management – AI systems must be maintained including retraining of algorithms. AI models need listed creation, re-validation, and expiration dates.

Principles for Organizations Deploying or Developing AI
1. Benevolence – Organizations must be committed to use AI systems for positive purposes.
2. Transparency – AI must be recognizable as such or must announce its nature. AI systems do not incorporate or conceal any special interests and deal even-handedly and fairly with all good faith actors.
3. Data Sources – Data used for AI must be of the highest quality, applied appropriately and purposefully (relevance), address merits and limitations when used, and adhere to FAIR principles.
4. Accountability – AI harm and unintended consequences must be reported, assessed, monitored, measured, and mitigated as needed. Response to complaints and redress must be guaranteed.

Principles to Address Special Considerations

1. Vulnerable Populations – AI applied to vulnerable populations requires increased scrutiny and appropriate community involvement to avoid worsening inequity in healthcare.
2. AI Research – continued research, and research funding into AI in healthcare is prioritized and required.
3. User Education - Developers of AI have a responsibility to develop, implement, optimize, and sustain educational resources and programs that educate healthcare providers and consumers on machine learning and AI systems used in healthcare settings.

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