

June 10, 2019

National Institute of Standards and Technology (NIST)
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Submitted electronically to: ai_standards@nist.gov.

RE: RFI: Developing a Federal Standards Engagement Plan. Artificial Intelligence (AI)
Technical Standards and Tools [Docket Number 190312229-9229-01]

Kaiser Permanente offers the following comments on the above-captioned Request for Information (RFI), published on May 01, 2019.

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with 12.2 million members in eight states and the District of Columbia.¹ Kaiser Permanente has implemented a secure Electronic Health Record (EHR) system, KP HealthConnect® to support the delivery of healthcare services to our members and to enhance communications among providers.

The RFI solicits input to help NIST understand the current development status, as well as challenges and opportunities for the availability and use of AI technical standards. NIST also seeks feedback about the current and future roles for Federal agencies related to the availability, use and development of these standards.

General Comments

Kaiser Permanente is committed to promoting innovative technologies that have the potential to transform the delivery of health care and improve patient care. We generally agree that artificial intelligence (AI) holds the potential to improve health outcomes, revolutionize the practice of medicine, and transform the patient experience. However, we are also concerned that the current

¹Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

regulatory and legal regimes have not yet evolved to anticipate how the use of AI could impact medical practice, care delivery, population health, and the health care industry.

We offer the following comments on selected questions below:

AI Technical Standards and Related Tools Development: Status and Plans (Section II – Questions 1 through 8)

Assessing the Need for AI Technical Standards and Tools

There are numerous areas where AI could be applied across the private and public sectors. Thus, we recommend that NIST should focus initially on prioritizing these needs before working on the various standards and tools to support them. For instance, NIST could begin this process by implementing a national, multi-sectorial survey to prioritize activities for AI applications within each sector and establish the need for such standards and tools.

An important consideration for AI standards development is the availability, accessibility, quality, reliability, and completeness of the underlying data. While an AI system's technical capabilities might be sound, applying AI to specific situations could yield poor results if the data are not valid and reliable for the intended purpose and population, such as incorrect conclusions about the value of certain treatments. Thus, addressing these aspects of data should be a critical component for AI standards and tools development.

NIST should also standardize definitions. For example, AI might be defined as computational systems using algorithms and data to address complex problems, or alternatively, as systems that can accomplish their tasks despite environmental changes, or systems that can adapt their algorithms to changing inputs and situations. The common understanding of an autonomous system is technology that can respond to real world conditions without human help. We recommend NIST consider autonomous systems and intelligent systems together; such definitions are important to circumscribe the scope of work and the effect of policies.

Technical Standards and Roadmap

The RFI (Questions 1-5) seeks examples of technical standards and tools plus the names of organizations that have developed those standards, and whether they are sector-specific.

The Institute of Electrical and Electronics Engineers (IEEE) is the world's largest technical professional association, with over 400,000 members in 160 countries, more than 50% outside the US. IEEE is a 501(c)3 standards development organization (SDO) that publishes standards accredited by the American National Standards Institute (ANSI), and it has over 700 technical standards under development.

The Council on Extended Intelligence (CXI) is one of IEEE's newest councils, joining its other seven councils and 39 technical societies. CXI's current focus is developing standards for autonomous and intelligent systems (A/IS) including methods for participatory design of A/IS and measuring societal benefits and risks of A/IS related to sustainable human progress. Other

IEEE societies and councils also have published many technical standards and are developing new ones that may be used in A/IS.

The International Standards Organization (ISO), an independent, non-governmental organization with 164 national standards bodies, brings together experts to develop voluntary, consensus-based standards to support international innovation. The International Electrotechnical Committee (IEC) is an international standards organization that focuses on development and maintenance of international standards for all electronic and related technologies.

The ISO/IEC Joint Technical Committee 1 – Information Technology (ISO/IEC JTC 1) focuses on information and communication technology and specializes further into sub-committees. Among these sub-committees are SC 40 and SC 42. The scope of ISO/IEC JTC 1/SC 40 is standardization of IT Service Management and IT Governance, such as audit, digital forensics, governance, risk management and other service-related functions.

ISO/IEC JTC 1/SC 42 focuses on AI. Among the activities SC 42 sponsors is developing reference architectures for the use of big data in AI. It also examines concepts in AI, including use of machine learning, bias in AI systems and AI-aided decision making, robustness of neural networks, and ethical and societal concerns.

SC 42 cooperates with SC 40 to understand governance implications for IT systems that use AI. SC 42 is the first international joint committee focusing on standardization activities for AI. It broadly considers the entire AI ecosystem, not just technical aspects. SC 42 has organized its work around five major areas: Foundational Standards; Computational Approaches and Characteristics of AI Systems; Trustworthiness; Use Case and Applications; and, Big Data Reference Architecture.

Defining and Achieving U.S. AI Technical Standards Leadership (Section III – Questions 9 through 12)

The U.S. is an active participant and leader in international SDOs focusing on AI. ANSI holds the Secretariat position for ISO/IEC JTC 1. In addition to its work with the ISO/IEC JTC 1/SC 42, the U.S. also actively engages in AAMI, IEEE and other SDOs that do AI-related work. INCITS – AI is a national body that serves as the U.S. Technical Advisory Group (TAG) representing the country to the JTC 1/SC 42, and is a proponent of the ISO/IEC JTC 1 standardization program on AI. However, the level of federal government involvement in these standardization efforts is not clear.

Limited work has been done in policy development related to AI, and the ethical considerations about the use of AI are subject to heated policy debates. IEEE CXI is a leader in development of frameworks and standards in this area, working in conjunction with the World Economic Forum (WEF), the Massachusetts Institute of Technology Media Lab (MIT), participants from other IEEE societies, and other SDOs.

Despite the current and potential importance of AI in health care, this sector is under-represented in standardization efforts. NIST should consider the government's role in ensuring balanced

participation from multiple sectors of the economy, including health care and public health. NIST should consider a possible role for itself as a convener or coordinator for cross-sector and cross-SDO planning and coordination of standards development related to AI.

Prioritizing Federal Government Engagement in AI Standardization (Section IV – Questions 13 through 17)

Unique Needs of Federal Government and Individual Agencies for AI Technical Standards and Tools

Historically, when federal agencies have mandated technical standards for use in healthcare, results have not been optimized for care delivery or most other functions of the health care system. Rather than specifying standards via regulations, the federal government would be more effective supporting the overall community of practice, defining functional requirements of AI, and encouraging the development and adoption of voluntary, consensus-based standards.

This approach is especially important for highly advanced, innovative, and rapidly evolving technologies such as AI. As an end-user of AI technology and standards, federal agencies must also be actively engaged as a stakeholder in the development and maintenance of these standards. Federal resources for AI standards development could support resources for evaluating AI tools, funding and encouraging private sector research and development of these tools, and funding centers of excellence in AI in both academic and industry settings.

Type and Degree of Federal Agencies' Current and Needed Involvement in AI Technical Standards

As noted earlier, federal agencies should actively engage in multiple SDOs, including CXI and INSITS (US TAG), to identify the need for new standards and to participate in the development and maintenance of such standards. Federal agencies continue to participate in the work of SDOs to develop, test, and implement standards in many different areas. For example, federal agencies are engaged in HL7 International, which develops health care standards. All these SDOs operate globally.

Prioritizing Federal Government Engagement in Development of AI Technical Standards and Tools

The federal government may prioritize the use of AI to help control increasing costs within certain sectors, such as health care. AI has the potential to reduce variability in treatment costs related to common diseases in certain geographic regions within the U.S. One use case that bears exploring is whether autonomous systems can help facilitate public health reporting, thus more rapidly identification of emerging infectious diseases within certain populations.

Adequacy of Federal Government's Current Approach for Engagement in Standards Development

We encourage the federal government to participate in SDOs and to partner with the private sector in developing its own consensus-based AI standards and tools when needed, for example, by establishing privacy and security frameworks to protect the integrity of health care data used for AI purposes.

Examples of Federal Involvement in Standards Arena

The Federal government plays a critical role in moving the health care system away from fee-for-service reimbursement towards value-based payment models. Recent changes in Medicare reimbursement policies have prompted the private sector to innovate payment models as well.

To update standards for health insurance administration and payment systems to better facilitate value-based care, the Center for Medicare and Medicaid Services (CMS) and private health plans are supporting the Da Vinci project along with participants the Office of the National Coordinator for Health Information Technology (ONC).

DaVinci is developing standards and implementation specifications for application programming interfaces (APIs) based on HL7 Fast Healthcare Interoperability Resources (FHIR) to create real time transactions for data exchange across communities, supporting value-based care scenarios. CMS participates on the Da Vinci Project Steering Committee. This is an example of how a federally-supported initiative is contributing to standards development to support federal policy goals, in this case encouraging value-based care.

Conclusion

Kaiser Permanente looks forward to working with NIST on the continual development of AI technical standards and tools. We appreciate your willingness to consider our comments. Please feel free to contact me (510.271.5639; jamie.ferguson@kp.org) or Lori Potter (510-271-6621; lori.potter@kp.org) with any questions or concerns.

Sincerely,



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