



November 27, 2017

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services

Re: ONC Interoperability Standards Advisory, 2018 Reference Edition

Dear Dr. Rucker:

Over the past year, AMIA's Public Policy Committee has considered the present and near-term policy landscape to develop Principles and Positions across select, priority domains that are essential to the emergent realm of public policy referred to as Health Informatics Policy.¹ 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.

Data standards and interoperability are essential components of the Health Informatics Policy domain.² As such, AMIA hosts an Advisory Group focused specifically on Health Information Technology (IT) Data Standards & Interoperability (available in [Appendix C](#)). This group led the development of Principles and Positions that support the vision of HIT interoperability and articulates the characteristics of standards that are useful, accessible, and can be implemented consistently across use settings. These Principles and Positions were endorsed by the AMIA Board of Directors earlier this year.

As you are aware, Health IT standards influence and enable capabilities for analytics and knowledge application in this information-intensive era of healthcare delivery. Increased capacity and ubiquitous use of analytics and knowledge-based treatments, in turn, increase the efficiency and effectiveness of healthcare, with great benefit to patients, payers, and public health.

However, despite the critical role of standards in system interoperability and data exchange, as well as widespread recognition of their importance, the uptake of standards in healthcare is varied and incomplete. Substantial variation across implementations hampers true semantic interoperability. Multiple coding systems exist, with overlapping content and different structures that are dynamic, voluminous, complex to implement, and difficult to compare. Proprietary, idiosyncratic, and custom coding systems remain in many organizations. There are competing standards for certain content areas, while gaps remain in others. There is no shared understanding for how multiple domain standards should be used to support the spectrum of activities across biomedical research, care delivery, and public health, leading to variation in how data are transformed from local coding

¹ AMIA Public Policy Principles and Policy Positions, 2016-2017 Priorities, available at: https://www.amia.org/sites/default/files/AMIA_2016-17_Policy_Priorities-Positions_170829.pdf

² Ibid. (pg. 13)

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systems to national standards and vice versa. There is also a gap in defining clinical standards that can be used interchangeably with basic research standards, limiting translational use of research discoveries. Further, identification of national standards involves a myriad of stakeholders, such as government regulators, health IT developers, publishing/journal editors, university promotion committees, and patient advocacy and consumer rights groups, among others.

The solutions to these challenges are not clear and will require the collaboration of numerous stakeholders to solve. The diverse membership of AMIA represents many of these stakeholders and we all share a vision of a world where information technology can support the delivery of quality and efficient health care. AMIA appreciates the efforts made by ONC to have an open conversation regarding the current state of biomedical data standards. In particular, the annual ISA process has given stakeholders a chance to discuss and debate the current state of standards for specific use cases. While recent enhancements to the content and presentation of the ISA have improved the capacity for stakeholder debate, there remains a need for unbiased, strategic leadership on the current status and future direction of health IT standards. We believe this leadership is best derived from private sector experience, with public investment and convening.

In this letter, we present **three key overarching recommendations to (1) Update and enhance the Nationwide Interoperability Roadmap; (2) Enhance testing and improve test tooling; and (3) Invest and align funding to improve health IT standards.** These recommendations are resultant from our Health IT Standards & Interoperability Principles, and are in response to the call for comment on the 2018 ISA Reference Edition. Our intent is that these Principles and recommendations will engender discussion over the future direction of health IT interoperability standards development, testing, implementation, and refinement, and inform the finalization of the ISA and other ONC activities in the future. While we realize that our recommendations do not align directly with the ISA structure and requested comments, we feel that the recommendations are important to ensure that any standards referenced in the ISA will be used consistently and prudently towards the goal of interoperability.

Recommendation 1: Update and Enhance the Nationwide Interoperability Roadmap

The Shared Nationwide Interoperability Roadmap³ produced by ONC in 2015 represents the most comprehensive review of current health IT interoperability, ongoing challenges, and potential paths forward. The Roadmap includes sections on certification, testing, semantic and syntactic standards, and services. In order for the ISA to contribute more fully to the national dialogue on health IT interoperability, we recommend that ONC update and enhance the Nationwide Interoperability Roadmap along several important dimensions, including:

- A detailed gap analysis of current and needed standards to address priority national use cases;

³ <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

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- An update to and articulation of how ONC will achieve an Industry-wide Testing and Certification Infrastructure; and
- A description of how federal investments are coordinated to make progress on the standards-related aspects of the Nationwide Interoperability Roadmap.

Recommendation 1a: Gap analysis of Current and Needed Standards

ONC should establish a dedicated roadmap for standards. This roadmap could be produced as part of updates / enhancements to the Nationwide Roadmap, or it could be produced as part of the series of supplements developed alongside the Nationwide Roadmap. A gap analysis is foundational to achieving a health information infrastructure that can support national health objectives given the large and dynamic context of biomedical data. This gap analysis should describe the relationship between standards and the target for stakeholders to adopt,⁴ as well as enable a more pointed discussion on what standard may be allowed to sunset and where the industry is moving. Clearly, the ISA is intended to provide some of this analysis (maturity, coverage and adoption) and will inform future standards. An overall vision and plan is needed, however, to ensure the coordinated development and implementation of standards.

Recommendation 1b: Prioritization around Important and National Use Cases

ONC should convene and coordinate discussions that identify important use cases to identify what standards are needed and in what combination to ensure interoperability. Often, standards are developed based upon scientifically interesting “edge” use cases, as opposed to high-priority and common use cases. We believe that this tendency has contributed to the current state in which standards and prevalent implementations are insufficient to achieve interoperability. For example, the implementation of the FHIR standard by at least one major commercial EHR vendor does not yet support patient encounters that are clearly needed for many use cases.

Beyond technical and next-generation use case development, ONC should also help organize a process to identify and articulate what health objectives are most important for the country, and use those health objectives to inform high-priority use cases as the context in which to identify, evaluate, and provide further guidance on the implementation of various standards. For example, if controlling the opioid epidemic is a national health priority, then our standards and roadmap should include ubiquitous, API-based access to prescription drug monitoring program information for opioids across institutions.

Recommendation 2: Enhance Testing and Improve Test Tooling

Thorough testing remains an unrealized aspect of our nationwide approach to standards. Very few standards undergo rigorous testing at the development-level or at the implementation-level. Both are critical if interoperability is to occur. Further, ONC’s Certification Program has relied on

⁴ http://wiki.hl7.org/index.php?title=HL7_CDS_Standards

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conformance testing, not true interoperability testing, which would test both the sending and the receiving of information. In our experience, this is a daunting problem that warrants prompt attention from ONC and standards development organizations (SDOs). For example, emerging evidence suggests that support for FHIR varies widely across EHR vendors, where there continues to be extensive optionality in many areas. The CDA quality checker is a good example of the kinds of tools that are needed, but we need a more robust, modern testing infrastructure for health IT standards.

Recommendation 3: Invest and Align Funding Towards the Goal of Improved Standards

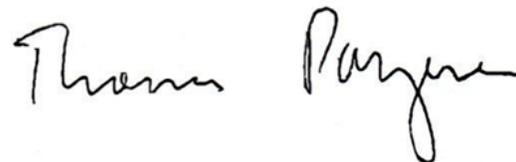
As a foundational principle, AMIA believes that health IT interoperability provides an enormous positive impact on society. Thus, AMIA recommends adequate funding for the development, management, testing, and maintenance of HIT standards, as well as the SDOs that create them. As the national dialogue continues in the direction of information models, and the use of ever-more nuanced vocabularies for various use cases, we recommend that ONC coordinate investment in terminologies and reference standards that might be used in combination. This investment could occur as part of the Interoperability Proving Ground,⁵ SITE,⁶ or as part of the 21st Century Cures mandate to develop an EHR Reporting Program.⁷ Another option would be to coordinate across federal agencies and offices that rely on or reference health IT standards. Regardless, sufficient and sustained investment by the federal government is necessary for interoperability to be achieved nationwide.

Below, in [Appendix A](#), we outline our position statements vis-à-vis the ISA in more detail. [Appendix B](#) includes the members of AMIA's HIT Standards Advisory Group. We hope you see AMIA and its HIT Standards Advisory Group as a collaborator and source of experts that can provide the variety of expertise (clinical, technical, and policy) that the ONC can leverage. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC for the opportunity to comment and look forward to continued dialogue.

Sincerely,



Douglas B. Fridsma, MD, PhD, FACP,
FACMI
President and CEO
AMIA



Thomas H. Payne, MD, FACP, FACMI
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

⁵ <https://www.healthit.gov/techlab/ipg/>

⁶ <https://sitenv.org/home>

⁷ Public Law 114-255, DEC. 13, 2016, 130 STAT. 1033

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Appendix A

AMIA Comments on the ISA 2018 Reference Edition vis-à-vis Health IT Data Standards & Interoperability Principles

AMIA Position Statements AMIA Supports...	AMIA Comments On the Interoperability Standards Advisory
<p>1. The development and management of HIT standards as a public good, operated in a nonprofit, non-proprietary basis, with low barriers to review, reference, or use.</p>	<p>General Comment: The ISA conveys information on the potential cost to use a standard and costs related to the testing tools. However, the ISA does not indicate whether standards are developed and managed as a public good via a non-profit entity.</p> <p>AMIA Recommendation: We encourage ONC to adapt the 2018 ISA by providing a section dedicated to SDOs that have responsibility for standards listed in the ISA, detailing their accreditation status (e.g. ANSI) and their tax status (e.g. 501(c)(3)).</p>
<p>2. HIT standards that leverage existing information technology stacks, such as the Internet Protocol Suite, to greatly expand the functionality of existing information systems, and increase the use of HIT standards by disparate systems.</p>	<p>General Comment: We applaud the endorsement of RESTful protocols in health data exchange and believe that they are a good example of this AMIA position statement. However, an outstanding issue is what to do with legacy standards that don't leverage widely adopted IT stacks. HL7 V2 and V3 do not use the most modern IT protocol stacks available. In particular, there is wide use of the CDA and V2 messages,⁸ which will require a clear plan for transition to current IT protocols. The FHIR specification is moving in that direction, but there will be many legacy standards that need this transition.</p> <p>AMIA Recommendation: This issue is so fundamental to the future of health IT interoperability and our national HIT infrastructure, that we call for funding and explicit discussion with appropriate experts to better leverage state of the art IT stacks.</p>

⁸ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

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<p>AMIA Position Statements</p> <p>AMIA Supports...</p>	<p>AMIA Comments</p> <p>On the</p> <p>Interoperability Standards Advisory</p>
<p>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.</p>	<p>General Comment: The format of the standards by data type in theory support modularity of substitutability, but the boundaries for use (in information models or specific applications) are not clear.</p> <p>LOINC and SNOMED CT (SCT) are recommended for the interprofessional longitudinal care plan and interoperability. ISA supports the use of any of American Nurses Association’s (ANA) nationally recognized terminologies⁹ for the user interface within EHRs, and for exchange of data, LOINC and SCT are recommended. To achieve this goal, ONC needs to continue supporting mappings of interface terminologies to LOINC and SCT to support the domain of nursing. However, SCT has the potential to be used in different ways, and CCDA specifications are misused and used inappropriately, which hampers interoperability.</p> <p>AMIA Recommendation: If there are recommended ways to implement terminologies, they should be made available (e.g. SCT for initial assessment) to assure consistency and interoperability.</p>
<p>4. HIT standards that are simple, parsimonious, and include documentation that is complete, comprehensible, readily available, and timely.</p>	<p>General Comments: These attributes of HIT standards (simple, parsimonious, with complete documentation) are not easy to ascertain with the information provided in the current ISA.</p> <p>We support the endorsement of FHIR in the ISA, which provides a great exemplar of what this position statement is all about. (FHIR has succeeded because it is simple.)</p> <p>The ISA does provide some clear examples of HIT standards that are simple, parsimonious, and have sufficient documentation. For example, RxNorm and LOINC are clearly successful</p>

⁹ <http://www.nursingworld.org/MainMenuCategories/Tools/Recognized-Nursing-Practice-Terminologies.pdf>

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<p>AMIA Position Statements</p> <p>AMIA Supports...</p>	<p>AMIA Comments</p> <p>On the</p> <p>Interoperability Standards Advisory</p>
	<p>with regards to these attributes. Other standards are more complex in their structure and possible interaction, leaving room for improvement of their surrounding specification and associated documentation. For example, SCT has documentation in how to use it in different contexts, but it's not adequate for implementers. There's a need for documentation to be available for specific use cases, such as integration documentation.</p> <p>However, although these specifications and documentation are truly vital for interoperability, it is not necessarily in the purview or capability of particular standards developers to know and provide specification for all the various uses. An entity or organization with both a broader vision and authority and a mission to support interoperability will have to take responsibility for this. The ONC could greatly enhance the ISA by painting an overarching framework for how standards fit together.</p> <p>AMIA Recommends: The ONC should aim to develop an overall model of how multiple standards should fit together to support the broader health IT ecosystem.</p>
<p>5. HIT standards that are fit for purpose within a declared domain, and clearly recognized and identifiable as the preferred standard.</p>	<p>General Comment: The current ISA does not easily address this.</p> <p>For example, under "Representing Patient Medical Encounter Diagnosis," there is no statement on pros /cons of SCT and whether or not it is preferred over ICD. The ISA should add more information about context of use.</p> <p>In addition, CDISC research standards are named for analytic data sets, but this is too broad and potentially misleading. These standards may be helpful for other purposes but only required for FDA-regulated studies.</p>

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AMIA Position Statements	AMIA Comments On the Interoperability Standards Advisory
AMIA Supports...	<p>AMIA Recommendations: The specific domain and context of use should be declared for each of the coding systems specified. For example, in the case of SCT under “Representing Patient Medical Encounter Diagnosis,” the ISA should state that for many decision support or research applications, SCT provides more granularity than ICD-10. The same is true for medical procedures encoded in SCT, versus CPT or ICD.</p>
6. HIT standards that leverage prevailing security practices to protect and preserve privacy and confidentiality.	<p>General Comments: We applaud ONC for including security information in the Appendix. A secure environment is a necessary condition for interoperability that includes personally identifiable health information.</p> <p>We note that security specifications are embedded in some standards (e.g. FHIR/SMART, CDA). Legacy specifications also have a range of security specifications, which can interfere with our previously stated principle of modularity, since each standard is expressing its own range of specifications, rather than leveraging a framework like OAuth 2.0.¹⁰ There is thus potential for overlapping or competing/contradicting specifications. Most importantly, however, this inclusion of security across standards can add complexity.</p> <p>AMIA Recommendation: If we have an overarching picture of how standards fit together (see point 4), then we need a unified framework for security that can be implemented consistently across use cases and components standards.</p>
7. Efforts to recognize and address stakeholder motivations, aims,	<p>General Comments: Standards developers need to be inclusive of user needs in order to increase the utility and uptake of the standards. This inclusiveness and engagement of users will</p>

¹⁰ <https://oauth.net/2/>

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<p style="text-align: center;">AMIA Position Statements</p> <p>AMIA Supports...</p>	<p style="text-align: center;">AMIA Comments On the Interoperability Standards Advisory</p>
<p>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.</p>	<p>require resources, but is presumably a worthwhile investment if the standards are widely used and interoperability is achieved. The development of standards that are responsive to user needs will be greatly enhanced by the identification and clear articulation of important use cases (mentioned in our letter as a high-level recommendation) and if the process for standards development is inclusive, transparent, and builds upon real world experience.</p> <p>AMIA Recommendation: The motivations of users of the standards should align investment with value and return, and the ONC can facilitate this as both a value case and a business case. Further, the ONC can encourage SDOs to adopt processes for standards development that are inclusive, transparent, and that build upon real world experience. Further, the ONC can facilitate the reporting of this information to the ISA so that users and implementers can consider this in implementation decisions.</p>
<p>8. Standards development that incorporates implementation experience and feedback loops from real-world settings to better support an adoption pathway for HIT standards.</p>	<p>General Comment: While this ISA open comment is a step in the right direction, there needs to be a forum for users to share specific and detailed implementation experience. The HL7Standard for Trial Use (STU) movement provides a mechanism for implementers to test and improve specifications before naming them as standards. We applaud the ONC for recognizing that there is a need to try new things, and to encourage the use of real world experience in the standards development process.</p> <p>Standards that are still in the early stage of trial use have been adopted earlier, but there is no closed loop from real-world settings. Implementation is different, (and should be) but there isn't a good way for SDOs and potential future adopters to know what has been done. The current structure does not indicate which standards have good feedback loops from real world processes. Further, the STU designation can lead to overlapping standards and potential confusion. For example, the CCDA STU is overlapping FHIR as a way to exchange</p>

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AMIA Position Statements AMIA Supports...	AMIA Comments On the Interoperability Standards Advisory
	<p>information. Guidance on when to adopt new standards, and plans to ensure interoperability between different exchange standards might be needed.</p> <p>AMIA Recommends: The ONC should support a reporting process to make it clear to users which standards have a feedback mechanism and processes to collect data and feedback about early implementation and testing experiences. Further, the ONC can provide guidance on when to adopt STU or new standards, and plans to ensure interoperability between different exchange standards might be needed.</p>
<p>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.</p>	<p>General Comment: Postel’s Robustness Principle states: Be conservative in what you do, be liberal in what you accept from others (often reworded as, “Be conservative in what you send, be liberal in what you accept”).¹¹</p>

¹¹ Postel, Jon, ed. (January 1980). Transmission Control Protocol. IETF. RFC 761.

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Appendix B

Members of AMIA's HIT Standards & Interoperability Advisory Group:

Chair, Christopher Chute, MD DrPH, Johns Hopkins University
Vice Chair, Rachel Richesson, MS, PhD, MPH, Duke University

Elmer Bernstam, MD, MSE, MS, UT Health
Olivier Bodenreider, MD, PhD, National Library of Medicine
Guilherme Del Fiol, MD, PhD, MS, University of Utah
Robert Freimuth, PhD, Mayo Clinic
Melissa Haendel, PhD, Oregon Health & Science University
George Hripcsak, MD, MS, Columbia University
Kensaku Kawamoto, MD, PhD, MHS, University of Utah
Howard Strasberg, MD, Wolters Kluwer Health
Bonnie Westra, PhD, RN, University of Minnesota

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Appendix C

HEALTH IT DATA STANDARDS & INTEROPERABILITY

AMIA Believes:

AMIA Policy Principles

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 common representation for each biomedical, clinical, and health data element 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.

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2. HIT standards that leverage existing information technology stacks,¹² rather than inventing healthcare-specific frameworks, in order 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.
4. HIT standards that support human readability, simplicity, parsimony, 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.¹³
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.
8. Standards development that incorporates implementation experience and feedback 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. A clear migration path for new standards as they are developed and implemented into HIT systems.
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.

¹² Such as the Internet Protocol Suite

¹³ This criterion implies being comprehensive within a declared domain of information, purpose and context, and generating verifiable content, preserving provenance, and computer interpretable.