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February 20, 2018

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at: exchangeframework@hhs.gov

Re: United States Core Data for Interoperability (USCDI)

Dr. Rucker:

AMIA appreciates the opportunity to comment on ONC's US Core Data for Interoperability (USCDI). We provide comments to the Draft Trusted Exchange Framework and Common Agreement (TEFCA) in a separate comment letter.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

As we understand it, the USCDI is a new mechanism to develop and disseminate national data policy by identifying priority data classes and establishing a process / timeline to make available such data classes for exchange. We also understand that forthcoming policy proposals, expected later in 2018, will articulate the technical specifications meant to support this data policy. As such, we will refrain from discussing known and potential challenges related to the interoperability of USCDI v1 data classes, except to say: (1) that making data available for exchange is necessary, yet insufficient for the interoperability of such data; and (2) data classes represented in the USCDI need to be part of Certified EHR Technology (CEHRT) collection capacities.

Standardization should not be prerequisite for data exchange

As a data policy for nationwide exchange, the USCDI is an important first step. It establishes a process for public feedback on priority data classes, and it is intended to make private sector stakeholders accountable for progress made towards those identified priorities. As an appendix to the TEFCA, we understand the need to constrain and prioritize specific data classes; however, this data policy begs a fundamental question: Is standardization necessary for exchange? AMIA as an organization, and informaticists by training, are fierce advocates for the standardization of data. In fact, AMIA has developed a set of Health IT Data Standards & Interoperability Policy Principles, beginning with the statement that "Clinical, research, and health information technology systems must be able to exchange biomedical, clinical, and health data consistently and reliably using computable formats while preserving the intended meaning and relationships."[1] However, we question the proposed approach of the USCDI, which does not make available numerous data classes for exchange until they are structured, several years in the future.

Discussions among members on priority data classes suggest there is a divergence of opinion over which data classes are most valuable and important.[i] Indeed, we suspect that multiple organizations will recommend that ONC prioritize many different types of data classes. To accommodate the varying priorities of multiple stakeholders, and to be consistent with the Cures Act,[2] **AMIA recommends ONC finalize the USCDI Version 1 with a policy that (1) enables the sharing of all data classes in computable and human readable (e.g. free text) formats, and that (2) gradually structures data classes over time.** This differs from the proposed approach, which requires data classes to be structured before sharing (see Figure 1 (current proposal) and Figure 2 (alternative proposal) below).

While we understand and support the need to prioritize data classes in the USCDI for programmatic purposes, a "share first, structure later" policy would allow all data classes not yet ready for inclusion in the USCDI to be exchangeable – even if it is only exchangeable as free text. A policy that encourages non-standard data class exchange ensures that important data does not remain behind closed systems, and it will help identify data classes that need to be prioritized for standardization. For example, if certain unstructured data classes are routinely sought after, this would be an important signal that standardization for this data class may be warranted. Further, this approach would support End Users who are at various stages of adoption/maturity to participate in the TEFCA. If a request is made of an End User to provide data for exchange, and that End User has not fully upgraded their CEHRT, this option would enable the End User to send such data in an unstructured format. While not ideal, the data is available for the receiving system to consume.

To support a "share first" functionality, we point ONC towards current and emerging Health Level Seven (HL7) standards, including the HL7 CCDA Unstructured Document, document-level template,[3] which provides a mechanism to share unstructured data, and/or several emerging FHIR resource,[4] to support this policy proposal, including:

- Patient
- Encounter
- Medication
- Observation
- Composition
- Conditions
- MedicationAdministration
- MedicationOrder
- ProcedureRequest
- Procedure
- ClinicalImpression
- DocumentReference

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[1] AMIA Policy Priorities. Health IT Interoperability Data Standards. Available at: https://www.amia.org/sites/default/files/AMIA_2016-17_Policy_Priorities-Positions_170829.pdf#page=13

[2] Section 4003 of Cures defines interoperability as allowing "for **complete** access, exchange, and use of **all** electronically accessible health information…"

[3] Health Level Seven. Implementation Guide for CDA Release 2.0 Unstructured Documents (2010) http://www.hl7.org/documentcenter/public/wg/structure/CDAR2_IG_UNSTRUCTDOC_R1_D1_2010JAN_keith_boone_20100111234228.doc

[4] Health Level Seven. FHIR Resource List. https://www.hl7.org/fhir/resourcelist.html

Figure 1: ONC's Proposed USCDI Expansion Process

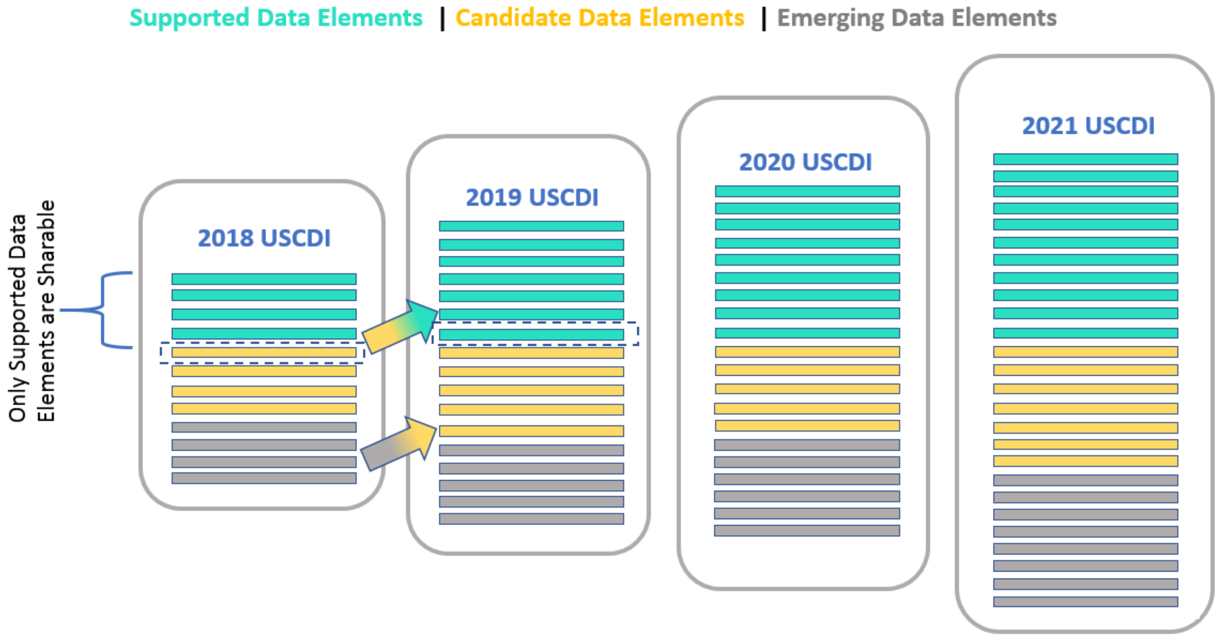
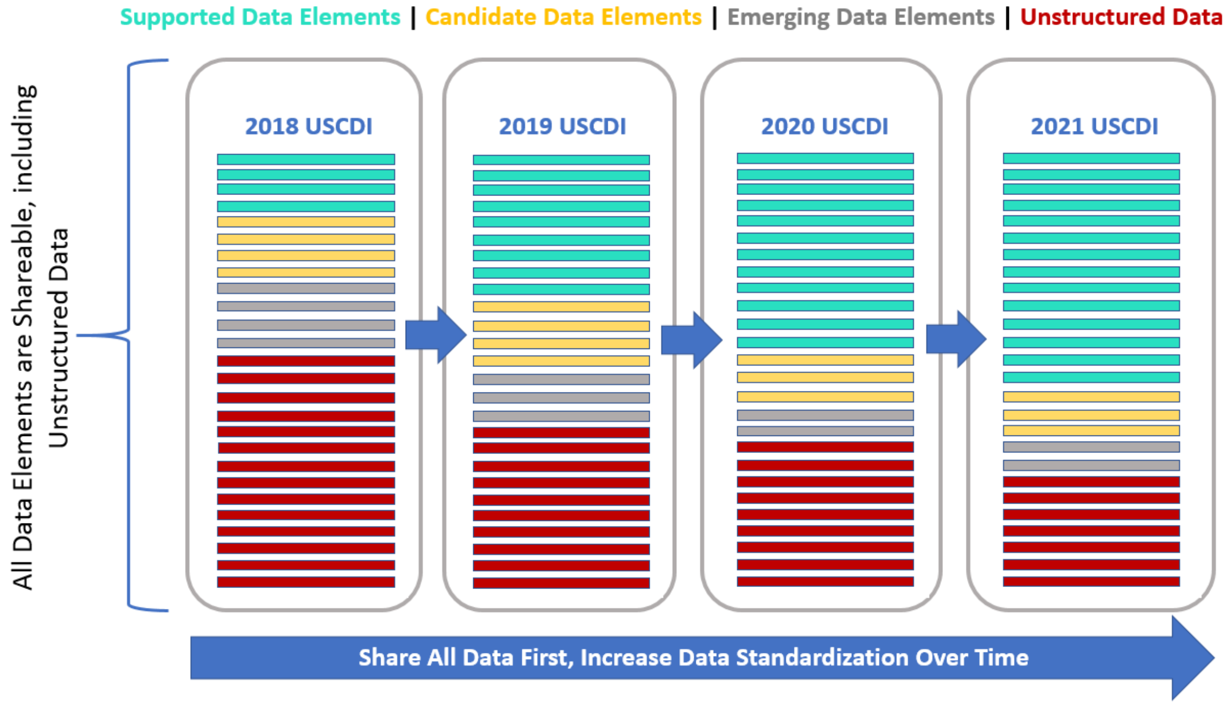


Figure 2: Share Now, Structure Later Approach using HL7 Unstructured Template / FHIR Resources



Data collection is an intervention that requires a cost-benefit analysis

Additionally, AMIA has previously called for a dedicated roadmap for health IT data standards, which includes a gap analysis of current and needed standards to improve interoperability.[5] We have also called for the development of a framework to better understand the relative costs and benefits related to data collection for quality measurement.[6] The USCDI could be an important component of both these recommendations.

In 2015, Baker, Perlin, and Halamka developed a framework that defined criteria, attributes, and metrics for evaluating and classifying technical standards and specifications as 'emerging,' 'pilot,' or 'ready for national standardization' based on their maturity and adoptability.[7] This objective framework was meant to help the Health IT Standards Committee understand which standards being considered for the Nationwide Health Information Network were mature and fit-for-purpose.

We recommend ONC leverage this important work, supplemented by the AMIA Health IT Data Standards & Interoperability Policy Principles[8] to develop a scorecard for USCDI data classes. This score card could inform the Interoperability Standards Advisory, and provide stakeholders with important context when trying to decide how to prioritize data classes. An important addition to this score card and objective framework would be consideration of a "cost to collect" estimate.

Data collection is an intervention that has both value and costs. The value of data collection is well-articulated for quality, safety, and other purposes, but the cost of data collection – in terms of time, money, and resources – is not. Recent studies have articulated the costs of certain activities, such as generation of clinical quality measures using EHRs,[9] but a more generalizable metric must be developed.

AMIA recommends that ONC work with partner agencies, including the Agency for Healthcare Research & Quality, the National Library of Medicine, National Institutes for Standards and Technology, and CMS, to develop a generalizable metric that captures the cost of data collection and identifies ways to leverage this metric in the USCDI, quality measurement, and other data collection activities.

In the same way that CMS and other payers rely on quality-adjusted life-years (QALY) to examine specific interventions, we must develop a similar measure to capture the cost-effectiveness of collecting electronic data. A QALY-approach would inform data collection efforts – for quality

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[5] AMIA Comment Letter to ONC on the Interoperability Standards Advisory, 2018 Reference Edition. Available at: https://www.amia.org/sites/default/files/AMIA-Comment-Letter-to-ONC-on-2018-ISA.pdf

[6] AMIA Comment Letter to CSM on the Quality Payment Program, Year 2. Available at: https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-QPP-Year-2-NPRM.pdf

[7] Baker D, Perlin J, Halamka J; Evaluating and classifying the readiness of technology specifications for national standardization, *Journal of the American Medical Informatics Association*, Volume 22, Issue 3, 1 May 2015, Pages 738–743, https://doi.org/10.1136/amiajnl-2014-002802

[8] AMIA Policy Priorities. Health IT Interoperability Data Standards. Available at: https://www.amia.org/sites/default/files/AMIA_2016-17_Policy_Priorities-Positions_170829.pdf#page=13

[9] Casalino LP, Gans D, Weber R, et al. US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures. Health Aff (Millwood). 2016 Mar; 35:401-6.

measurement and a host of other activities, including the USCDI. For example, some data classes are easy to collect, but of little value to the patient;[10] some data are easy to collect, of little value to the patient, but valuable at the population-level;[11] other data classes will have a high value for both patients and populations, but be overly costly to collect routinely.[12] There may be additional concepts, such as the Number Needed to Treat (NNT), that may be worthwhile to incorporate as well.

The NNT signifies how many patients would need to be treated to get one additional patient better who would not have gotten better without this particular treatment. The data collection equivalent would try to ascertain how many data would need to be collected to inform a decision that would not have otherwise been arrived at.

Together, the concepts of QALY and NNT could help inform which data elements are likely to yield the most return for collecting, and this metric would help stakeholders assess data collection pros/cons using a common methodology and nomenclature.

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Below we articulate the data class priorities as identified by AMIA members in Appendix A. 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,

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President and CEO
AMIA

Peter J. Embi, MD, MS, FACP, FACMI
President & CEO
Regenstrief Institute
AMIA Board Chair

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[i] AMIA will transmit detailed recommendations regarding the prioritization of data classes to ONC in a separate report.

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[10] e.g. Smoking Status
[11] e.g. Smoking Status
[12] e.g. Genomic data