December 20, 2018

Chesley Richards, MD, MPH, FACP
Director
Office of Public Health Scientific Services
Centers for Disease Control and Prevention
Department of Health & Human Services

Submitted electronically to Lauren Peel at ijt9@cdc.gov

Re: Request for Information National Test Collaborative 75D301-19-Q-69537

Dear Dr. Richards:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding this Request for Information (RFI) on a National Test Collaborative (NTC). AMIA is the professional home for more than 5,500 informatics professionals, representing researchers, front-line clinicians, public health experts, and educators who bring meaning to data, manage information and generate new knowledge across the health and research enterprise.

AMIA believes testing of HIT systems should test both conformance to the standard and interoperability of the standard to ensure data consistency and reliability across implementations. This belief, articulated in our Policy Principles and Positions,[1] leads us to support both:

- Standards development that incorporates implementation experience and feedback loops from real-world settings to better support an adoption pathway for HIT standards; and
- Interoperability testing, which tests both the sending of data using a specific standard(s) as well as receipt of data using such standard(s), consistent with Postel's Principle.[2]

AMIA greatly appreciates the Centers for Disease Control & Prevention (CDC) for fielding this RFI and identifying the need to "test true interoperability across EHR platforms as well as different clinical organizations in situ."[3] Despite our support for such an endpoint, AMIA urges CDC to begin with a narrow scope that is initially developed for a single purpose. Starting with a limited pilot will enable the NTC to learn how to establish and coordinate relationships among various stakeholders, including health IT developers, clinician users, clinical informatics experts, healthcare

[1] AMIA. Health Informatics Policy Principles. 2018. https://www.amia.org/public-policy/policy-priorities
[2] Also known as Postel's Robustness Principle, stating: 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"). Postel, Jon, ed. (January 1980). Transmission Control Protocol. IETF. RFC 761. Retrieved June, 2017.
[3] CDC. Request for Information (RFI) Number: 75D301-19-Q-69537. Pg. 1

organizational leaders, standards developers, measure stewards, and others. A limited scope will also improve the sustainability of the NTC by increasing the likelihood of tangible outputs and outcomes from which to incorporate into future focus areas.

Below we outline various considerations for the NTC based on our interpretation that the RFI has three potential application areas: (1) clinical decision support (CDS); (2) electronic clinical quality measurement (eCQMs); and (3) "other clinical testing." We do not recommend that the NTC look to address more than one of these application areas initially.

A focus on eCQMs would benefit from existing organizations, processes, and address a high-priority need. Establishing the NTC based on the use case of eCQMs may be relatively easy and quick given the existing environment. For example, were the NTC to focus on testing eCQMs in situ it would benefit from a socio-technical infrastructure of processes to endorse eCQMs and encourage widespread use of measures through regulation. Unfortunately, these same organizations and processes have various associated constraints that could hinder the NTC's impact and long-term sustainability.

A focus on CDS use cases would fill existing gaps in testing infrastructure as well as serve to convene various stakeholders to establish processes. Where the NTC could benefit from a relatively mature environment with eCQMs, CDS does not have the same kind of environment. However, it is possible that this environment could enable the NTC to have a greater impact on the evolution of similar structures for CDS. It is likely that a focus on testing CDS in situ would require a longer timeline to see such impact given the currently disparate stakeholders and lack of established structures.

As it relates to "other clinical testing," AMIA is supportive and interested in helping CDC and other federal agencies operationalize in situ health IT testing. Specifically, interoperability testing of specific kinds of transactions that utilize Certified EHR Technology (CEHRT) would greatly improve the usability and utility of clinical data. We view ONC's work in this area as essential, yet incomplete, since the Certification Program only tests conformance to a standard, not interoperability of that standard.

We note that new requirements from the 21st Century Cures Act will require CEHRT to have "successfully tested the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed," as part of new Conditions and Maintenance of Certification. We are eagerly awaiting final rules implementing this provision of Cures and we envision that once an NTC is established, such testing could represent an important set of use cases.

Finally, we offer a word of caution. Testing real-world, EHR-derived health IT scenarios – no matter what the use case – will involve organizational and legal structures that lab-based testing does not. These additional dimensions will likely mean that only the most motivated individuals and organizations will engage with the NTC on a voluntary basis, given the difficulty and uncertainty of

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in situ testing. We encourage CDC to think about various incentives that sister agencies within HHS can provide to testing participants, such as CMS payment policy and ONC Surveillance capacity.

Below, in Table 1, we outline our recommendations in more detail, and we address CDC's specific questions related to this RFI. 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 CDC for the opportunity to comment and look forward to continued dialogue.

Sincerely,

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

Enclosed: AMIA Comments on the Request for Information National Test Collaborative

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Table 1

REQUESTED INFORMATION

To help inform approaches CDC can apply with respect to setting up a NTC that can support robust clinical testing needs, please respond to the following questions in order:

RFI Questions	AMIA Response
Please confirm the examples in the background section and identify additional examples of clinical testing needs that could be met with a NTC. How could CDC design and execute a national testbed infrastructure that can support all the clinical testing needs identified? Please consider the importance of an agile development approach in the design and execution of a NTC.	While the RFI background contains appropriate examples, it omits mention of the National Institute of Standards & Technology (NIST). Members note that the CDC already partners with NIST on a test tool called the Forecasting for Immunization Test Suite, or FITS. We also note that in the identified realms of eCQMs and CDS, there are several projects meant to improve those artifacts, such as Cypress and the NQF Measure Incubator[4] (for eCQMs), JIRA (for CEHRT), and AHRQ's CDS Connect. We also note that there are efforts to de-identify data from live environments and/or mimic live patient data. Efforts related to the latter already exist with the Synthea™ patient generator.[5]

[4] https://www.fbo.gov/index?tab=documents&tabmode=form&subtab=core&tabid=17f575a812384339e3da3f54f9039f0f
[5] https://synthetichealth.github.io/synthea/

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Should a phased approach be considered to accommodate all the clinical testing needs? For example, should the initial scope of the testing begin with CDS, eCQMs, and a limited number of additional health IT and then expand to more types of health IT?	AMIA is fully supportive of a phased implementation approach. As outlined in our comment letter, we see a phased approach that begins with a specific and defined area increases the likelihood of success. We note that even between eCQMs and CDS, which are using common standards (e.g.CQL) to construct them, each artifact has very different testing requirements, and the organizations supporting them are very different.
Should a NTC support testing needs beyond those related to clinical care? If so, what kinds of additional testing needs should it support?	Beyond clinical care, AMIA encourages CDC to also include testing needs related to public health reporting and surveillance and population health.
What types of organizations, expertise, resources, etc. need to be part of the NTC in order for it to be viable, useful, and effective? Please expand on aspects such as organizational size or location, availability of certain resources (e.g., small clinical practices may not have IT teams), and other areas that can affect the ability to implement various kinds of health IT.	While CDC indicated that its "focus is more on ensuring the tools work in practice and less on conformity to standards,"[6] AMIA believes that CDC must include standards organizations, such as HL7, as part of the NTC. Inclusion of a standards organization will help in identifying where there are gaps in standards for health information. Further, we note that since AMIA is the professional home for clinical informatics, we have a range of board certified specialists who also are informatics experts. Finally, we encourage the NTC to engage with vendors and healthcare organization leadership (CIO, CMIO, CNIO, etc.) who will be necessary to prioritize any and all in situ testing, regardless of focus area.

[6] https://www.fbo.gov/index?tab=documents&tabmode=form&subtab=core&tabid=17f575a812384339e3da3f54f9039f0f

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What type of governance model(s) would be needed to operationalize a NTC? Please identify the functions, resources, barriers, facilitators, policies, and other aspects needed in your suggested governance model(s).	The governance model for the NTC should be developed and informed by the participants that comprise the NTC. We reiterate the need for SDOs, informatics experts, vendors and clinicians to be have a central role in the governance of the NTC.
How can the NTC be developed to be sustainable for the long-term?	We reiterate the need to have a narrow focus, initially, to develop ROI and demonstrate value. Should the NTC deliver value over time, it will be sustainable. Initial funding from the federal government will be necessary.
What would a successful NTC look like? What kinds of metrics should be tracked to evaluate this success (e.g., return on investment (ROI) or other endpoints)?	CDC should set benchmarks for diffusion across health care organizations and use these as metrics of success.
Are there any additional considerations for a national testbed infrastructure that were not captured in the previous questions? If so, please identify them and provide supporting information on (a) why those items should be included, (b) what types of organizations and resources would be needed to support those items, (c) what the downside would be if they were not included.	

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