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The American Medical Association (AMA) appreciates the opportunity to respond to the Centers for Disease Control and Prevention's (CDC) request for information (RFI) on a National Test Collaborative (NTC).

Health information technology (health IT) is a central component of health care. Exchanging and analyzing medical data can enhance and refine physicians' understanding of patient health. Patients and their care team can use health IT to inform decision-making and apply up-to-date scientific evidence to accurately and consistently improve health and wellness. The entire health system can improve by using health IT to monitor and measure patient outcomes. These are important components in achieving the "quadruple aim"—better care, lower total medical costs, more satisfied patients and more satisfied physicians. However, these goals are jeopardized when health IT systems fail to perform as expected. To that end, testing is key to ensure that health IT systems assist in, rather than detract from, achieving the quadruple aim.

The AMA strongly agrees there is a need for increased attention on health IT testing, particularly in real-world environments. The Office of the National Coordinator for Health IT's (ONC) health IT certification program is generalized around health IT conformance to federal certification criteria affiliated with Centers for Medical and Medicaid Services' (CMS) reporting programs (e.g., Promoting Interoperability). Unfortunately, these programs do not accurately reflect clinical workflows; they were established without a clear goal in mind, and ultimately lack emphasis on health system needs. Developing, testing, certifying, and using health IT for compliance and reporting reasons—instead of focusing on patient care—is a reason why the health care system has struggled in reaching the goals of interoperability and usability of electronic health records (EHR). Moreover, since testing is done in controlled laboratory environments, ONC's program does very little to assure products will perform as expected once they are installed in clinical environments.

The AMA agrees with the CDC that ONC's programs, along with those identified in the RFI's background, neither specifically address health IT implementation in actual clinical environments nor do they test in real patient care scenarios. We agree that real-world testing leads to better functioning products. **We stress, however, that CDC should also consider unintended consequences of establishing a testing environment without a principled focus on the goals or practical needs of the end use of health IT.** We note that testing is a complex, multidimensional, and often incremental problem where the use of multiple environments for conducting testing may be appropriate. Thus, we suggest taking a focused approach to address core testing needs of the health IT industry and its users. The CDC has correctly identified the need for electronic clinical quality measures (eCQM) testing. The AMA agrees and recommends this be the focus of the NTC.

To support the CDC's efforts in developing the NTC, the AMA, in collaboration with the PCPI Foundation, is providing the following responses to RFI questions. We believe these will assist in scoping a testing center focused to address practical needs of the eCQM community.

1. 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.

   The examples in the background section are supportive structures that help promote interoperability of health IT. They may also provide important testing attributes to improve new standards (such as Fast Healthcare Interoperability Resources or FHIR) to promote innovation.

   However, a national approach to testing eCQMs remains an important need. CDC could design a national testbed infrastructure for testing eCQMs either by creating its own designed, developed and managed testbed of key stakeholders (i.e., clinical sites, health IT vendors, platforms, data aggregators) or by facilitating the development of a network of organizations who are interested in doing this work—acting as essentially a health information exchange of eCQM testing networks.

   In addition, the AMA has established the Integrated Health Model Initiative (IHMI)—a collaborative effort that supports a continuous learning environment to enable interoperable technology solutions and care models that evolve with real-world use and feedback. IHMI combines clinical expertise and informatics to incorporate meaningful data elements around function, state, and patient goals. Leveraging a collaborative community, physician-led validation process and data model, IHMI provides the ability to rapidity develop clinical content necessary for eCQM creation and testing. We recommend the CDC include the IHMI as a collaborator in the NTC.

2. 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?

   Yes. A phased approach offers the opportunity to methodically design, build and expand on clinical testing needs. It offers a potentially faster method of putting a practical solution in place that can be immediately useful for the health IT community. The AMA recommends that the initial scope of testing start with eCQMs (either EHR or registry-focused) because of their nationwide use, importance in overall health system improvement, and prevalence in quality payment programs. eCQM testing brings multiple technology sources in contact with each other (e.g., data warehouses interacting with EHRs and quality measure logic) and promotes fundamental interoperability needs (e.g., data models and consistent medical terminology utilization). Starting with eCQM

testing will naturally incorporate various health information technologies. The AMA strongly suggests focusing on direct delivery of clinical care and expanding to peripheral or ancillary technologies as needed.

3. Should a NTC support testing needs beyond those related to clinical care? If so, what kinds of additional testing needs should it support?

   Expansion of the testing scope to "process of care improvement" (i.e., financial, administrative and operational improvement domains) may be warranted. We stress that a clear goal of supporting core testing needs of the health IT industry and its users be the driving factor, with the initial focus on eCQMs.

4. 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.

   In order to be representative in eCQM testing, a diverse range of organization types, sizes, and geographic locations across the United States should be included in the NTC. Organization types should include the PCPI Foundation, eCQM developers; physician office practices and groups; federally-qualified health centers (FQHCs); small, mid-sized and large hospitals; academic medical centers; integrated delivery networks (including mental health organizations); payer organizations; research institutions; drug and device manufactures; consumer groups; long-term care (hospice, nursing homes); nursing practices; and public health organizations and departments. In particular, rural organizations should be represented.

   As above, we stress that having physicians be a part of the NTC is necessary for the NTC to be viable, useful, and effective. Physician input is needed to ensure that any real-world testing that is complex and multidimensional accurately contemplates the clinical workflow and does not increase administrative burden.

   This representation should be reflected in NTC governance and in the types of organizations that conduct eCQM testing. The NTC itself needs data science professionals, informaticists, quality measure methodologists, and traditional IT staff.

5. 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).

   Oversight and partial funding of the NTC may best come from a federal entity (e.g., CMS, CDC, or another Department of Health and Human Services (HHS) agency). HHS agencies have the influence, reach, and impartiality necessary for such a collaborative to be successful. Federal agencies could also provide initial funding for the design,

development, and implementation of the NTC with additional revenues coming from users of the NTC itself.

NTC functions should include:
- Growing, managing, and maintaining the NTC database of collaborators and test sites;
- Establishing a funding, development, and growth plan for the NTC;
- Promoting the NTC among stakeholders, prospective stakeholders, and clients; and
- Establishing and fostering relationships with health IT vendors to facilitate testing projects.

The NTC will need ongoing resources, including:
- Leadership and administrative support staff;
- Technology (e.g., warehousing, cloud-based/distributed computing, software); and
- Support from consultants or experts to develop, design and implement a business model to ensure NTC sustainability.

Potential barriers include:
- Securing initial funding, especially if the NTC is a government-run entity;
- Conflicts of interest among stakeholders;
- Lack of trust among the stakeholder community, which could limit sharing of critical information useful to advance the work of the collaborative;
- Consensus on standards and use (e.g., clinical, terminology, etc.); and
- Changing measure testing requirements (e.g., difficulty in keeping up with and effectively using sites for eCQM testing).

Necessary facilitators include:
- Operations leadership;
- Stakeholders who will support the growth and development of the NTC;
- An HHS sponsor to champion the NTC; and
- Partners with an interest in *patient health care*, not necessarily the health care industry. These stakeholders can provide unique perspectives to facilitate growth, expansion, and overall success of NTC.

6. How can the NTC be developed to be sustainable for the long-term?

The NTC must be established with these attributes in mind:
- Strong leadership and committed stakeholders;
- An entity that serves the testing community's needs and continues to be relevant to the community as it changes;
- Ability to stay abreast of the changes at the national level that affect measure testing;
- A viable revenue generation model (e.g., membership dues, fees for accessing data possibly with a "freemium model"); and

- Value to stakeholders (e.g., a less costly or more efficient way of testing, real-world testing data, easy to access and use test sites, or pre-negotiated terms and contacts with sites enabling "turn-key" solutions).

7. 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)?

   NTC success will hinge on ease-of-use and access for measure developers, with a focus on easily-identifiable suitable sites for testing projects. It must facilitate testing both quality measures within health care delivery organizations and quality measures using real-world data. The NTC should provide education to test sites to ensure a consistent understanding of what quality measures are and what should be expected in a measure testing project. A successful NTC is also financially-viable, putting into place a business model not solely dependent on grants or federal funding. It must contain a diversified set of revenue streams. For example, stakeholders would pay a fee to belong to the NTC, measure developers would pay a fee to use NTC test sites for measure testing. The NTC could potentially develop fee structure for others who are interested in accessing NTC data. The NTC will also promote fair-pricing for its members, ensuring competitive pricing to access aggregator data. Finally, a successful NTC has a large user community with opportunities to learn and share best practices. An NTC annual or biennial conference may also serve to strengthen the community.

8. 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.

   Technology-oriented test sites with established data reporting and staffing capabilities will be important in this endeavor. At the appropriate time, the NTC should also consider expanding its mission and recruit sites that are less tech-oriented, but for whom measure testing would be important. Once a robust center is established, NTC could aid less tech-savvy organizations whose needs are typically underrepresented in the measure testing process. Support for design and development of measures unique to these organizations' populations will increasingly become important.

The AMA appreciates the opportunity to provide these recommendations and looks forward to working collaboratively with the CDC on the NTC. If you should have any questions regarding this letter or would like to discuss our comments further, please feel free to contact Matt Reid, at matt.reid@ama-assn.org.