

Health Information Technology Standards Committee

DRAFT

Summary of the May 24, 2012 Virtual Meeting

KEY TOPICS

1. Call to Order and Opening of the Meeting

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the meeting of the HIT Standards Committee (HITSC). She reminded participants that it was a Federal Advisory Committee (FACA) meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available on the ONC Website.

2. Opening Remarks

Farzad Mostashari, National Coordinator, remarked that the agenda reflected a focus on ease and scalability of technical support—vocabulary mapping, value set repositories, and moving point-to-point trust to conditions of trust, which eliminates the need for negotiation between two parties. Query Health represents automation and maturation. It is now technically possible to do many things. Now the work is to make it effortless. He reported two organizational changes at ONC—the establishment of the Office of Chief Medical Officer and the Office of Consumer Health. Jacob Reider and Lygeia Ricciardi have been appointed as acting respectively. Inspired by the Family and Consumer Power Team, a meeting has been organized for June 4 on standard use cases. Standards-related issues to move consumer use forward will be discussed.

3. Review of the Agenda

Jonathan Perlin, Chair of the Committee, spoke on four topics. First, attendance at a recent meeting of a cancer foundation in D.C. made him realize the many use cases made possible by Meaningful Use. The work on standards and interoperability of health information has contributed to the remarkable progress toward more personalized and precise cancer care. Jim Walker, who attended the same event, reported that a wide perspective of stakeholders had generally agreed to work on core principles. Perlin asked members to think about the capacity of the foundational structure that has been developed and its second order uses. Second, he recognized the work of the Family and Consumer Power Team and commented on the importance of ensuring the consumer's viewpoint in other work. Leslie Kelly Hall reported that the Family and Consumer Power Team had open action items pertaining to patient identity and matching. The Team created documents but the standards for patient facing systems and another area are outstanding. She asked for suggestions, reminding them that the HITSC had agreed that standards can sometime invigorate policy. Perlin asked ONC staff to work with her to achieve the desired ends. Third, Perlin referred to the summary of the April 2012 meeting. He asked for objections and corrections. Hearing none, he declared the minutes of the April 2012 meeting approved.

Action item #1: Chairperson Perlin declared the minutes of the April 2012 meeting approved with no changes.

Finally, he reminded the members to identify themselves when speaking and to mute their phones.

4. Comments

John Halamka, Vice Chairperson, said that the presentations deal with how to streamline trust issues, which will eventually eliminate the legal negotiations involved with data sharing and other activities. He informed the members that he had offered the records of his medical center to Rich Elmore for Query Health.

5. Briefing on ONC's Request for Information (RFI) on Governance for the Nationwide Health Information Network (NwHIN)

Steve Posnack, ONC, reported that the RFI reflects the work of HITSC and the Health Information Technology Policy Committee (HITPC). He mentioned that he assumed members had read the RFI and/or seen one of his presentations and slides. The RFI attempts to determine where ONC can add value. ONC wishes to create a foundation for long term national information exchange with a governance mechanism that puts in place the building blocks for all types of exchange. He also noted that the Notice of Proposed Rulemaking (NPRN) preamble refers to a governance mechanism being necessary for the transitions of care objective. The RFI focuses on the entities that facilitate electronic health information exchange. A voluntary framework is described. ONC seeks comment in five areas:

1. The establishment of a set of conditions for trusted exchange (CTEs) – “rules of the road”
2. A validation process for entities to demonstrate conformance to the CTEs (and subsequently become an NwHIN Validated Entity (NVE))
3. Processes to update and retire CTEs
4. Establishment of a process to classify the readiness of technical standards and implementation specifications to support interoperability related CTEs
5. Approaches for monitoring and transparent oversight

Sixteen CTEs are categorized into safeguards, interoperability and business. He acknowledged that they may not be all inclusive and invited members to comment on additional CTEs. Also, the CTEs could be packaged in some way for validation. He briefly moved through the slides that stated the 16 CTEs. He continued, saying that validation is an umbrella term. CTEs likely will have to be validated differently. Policy-related CTEs are different from technical standards. He explained that the structure for validation is similar to that used in the permanent certification program with one accreditation body and several validation bodies. He described a process for updating and retiring CTEs through which they could be classified as emerging, pilot or national, the latter meaning CTEs that are sufficiently mature to propose via rulemaking. ONC would share responsibility with other federal agencies, such as Federal Trade Commission (FTC) and the HHS Office of Civil Rights.

Q and A

Posnack clarified that ONC would approve one entity as the single accreditation body. It would not be a government agency.

Discussion ensued about accreditation, validation and certification and the scope of each.

Mostashari explained that to ONC staff the distinction between accreditation and validation makes sense. Accreditation applies to organizations; certification applies to standards, and validation is a pathway and the final point. Posnack observed that there could be other interpretations of the terms. Wes Rishel announced that he was not concerned with structure. However, the many workgroup calls indicated that the distinction is not clear to members. There is a question about the degree to which the validation process mirrors certification in Meaningful Use. Meaningful Use standards are set by law and certification standards are determined by the National Institute of Standards and Technology (NIST). The certification bodies have little discretion in determining requirements: Is this the same for validation specificity? Mostashari responded that ONC seeks comment on the issue. The goal is a framework that works nationally. The use of a validation body ensures trust and consistency. One could imagine a setting in which trust is more the responsibility of certification bodies. And the certification bodies may have different methods. According to Mostashari, ONC wants comments on the tension between greater standardization at the accreditation level or less standardization that allows for more innovation. Rishel opined that adding discretion to validation bodies may result in a race to the bottom.

David Kates inquired about envisioning various levels and types of services across NVEs either short or long term. Posnack replied that packages could possibly be developed, such as a small, broadly applicable starter set that would be validated for sets of services. Mostashari indicated that the three types of CTEs are linked. Specific services may be linked with specific policies and standards. A basic package could be combined with additional sets of services.

Halamka reminded everyone that governance is being planned for entities yet to be designed.

Kelly Hall asked about patient and consumer participation. Mostashari pointed out that the subject of the exchange is the patient. A third party that is selected as a Personal Health Record (PHR) vendor could be an NVE. Patient access is one of the NVE activities. Patients should be highly interested and empowered partners.

Dixie Baker said that she wished to follow up on the debate with Rishel. She reported that the Privacy and Security Workgroup and the NWHIN Power Team observed that the CTEs vary considerably; some are high level policy and others are specific standards. Did ONC consider a tiered approach in which the lower levels (technical standards) would be certified? Posnack invited comments on the topic. Some CTEs represent maturity; others require additional specification. There is potential to level certified technology. Mostashari observed that a provider would select an NVE because it works for everything that needs to be done. Where else would specificity come from? The standards can be set out in rulemaking, test scripts, accreditation, or validation. He asked the members to think about these differences and how conflict among validation bodies would be resolved.

Baker stated that her groups want specifics but they recognize that governance policy changes less frequently than do standards. Different types of organizations can deal with policies and standards respectively. Therefore, two levels are needed with a distinction between validation of

the organization and certification of the standards. Following more back and forth, Arien Malec referred to his participation in several workgroups to which RFI questions were assigned and said that Baker is trying to set up a framework that recognizes variation in CTEs lifecycles.

Halamka pointed out that the members were debating issues expected to be addressed under the next two agenda items.

Walker asked that ONC think about parsimony and the costs incurred in validation for a compliant organization. Mostashari said that a policy goal is market competition, which will result in lower costs and higher quality. Walker expressed concern about small, resource limited organizations that will be very affected by cost. He said that one cannot write enough CTEs to assure the process will work.

Cris Ross pointed out that the RFI does not state what works for what purpose, which he advised should be the next step. Other industries can be examined. ISO standards are fundamental. Organization will go beyond certification and validation to consider services. He indicated agreement with Walker. Mostashari responded that customers can do due diligence on NVEs but a package for direct exchange will enable stage 2 quickly. A customer will not have to wait for its NVE to negotiate with another NVE. Kelly Hall opined that government can never replace due diligence. The market has its own rewards.

Rishel observed that although the collection of CTEs has specific subsets applicable to specific use, the RFI does not state the goal that each NVE can handle all CTEs. He stated that the reduction of cost is a more realistic goal.

Marc Overage talked about costs. The costs of implementation of particular tools will vary across organizations. The real costs may be in adaptations. Rishel said that mapping should be the only variable cost. Mostashari acknowledged that the RFI does not tackle mapping.

6. Report from NwHIN Power Team

Criteria for Assessing Standards and Specifications

Dixie Baker, Chair, used slides to remind the members of the scope and approach of the team. She referred to the evaluation criteria defined in the summer camp of 2011. Of those criteria, ONC staff removed “need” because it is in itself a condition for specification. The team added “components” to clarify that a specification is likely to incorporate more than one technology component. “Deployment/Operational Complexity” was split into two separate criterion—ease of deployment and ease of operations. They added “intellectual property” as a new criterion. The team has defined metrics and identified attributes for two evaluation criteria—maturity of specification and maturity of underlying technology components. Work on the other four criteria is in draft stage. Work was interrupted due to the assignments of commenting on the RFI. Baker distributed an appendix, saying that she would appreciate comments.

Preliminary Comments on RFI

Baker reported that the RFI reflects the team’s work during the summer camp in 2011 and the CTEs are related to the ongoing work on evaluation criteria. The RFI poses 66 questions, 22 of which were assigned to the NwHIN Power Team. Although the team has not completed its work, Baker showed and reviewed slides that listed the preliminary responses for the questions that have been discussed to date. General comments were:

- RFI does not effectively convey an overall vision for the NwHIN

- RFI does not adequately define terminology – e.g., RFI defines NVE “validation” as encompassing both accreditation and certification, without defining any of these terms
- The governance process described in the RFI mixes policy-level requirements and processes, with technical-implementation-level requirements and processes

She then read the specific questions and accompanying response.

Question 39: What standard of availability, if any, is appropriate?

Availability requirements are service-specific; so it would not be realistic to specify a single availability level across all services and NVEs. We question whether there is a market failure that really compels a standard for availability. We think transparency is more important than establishing a specific availability floor; especially publication of actual availability over time. Better to leave specific availability level as a contract provision.

- Some CTEs are too specific (e.g., transport standards, certificate discovery standards) and are likely to change more often than policy
- We think validation of NVEs against governance policies should be separated from certification of conformance against technical specifications

Question 45: What types of transport methods/standards should NVEs be able to support? Should they support both types of transport methods/standards (i.e., SMTP and SOAP), or should they only have to meet one of the two as well as have a way to translate (e.g., XDR/XDM)?

1. The Condition does not address all the reasonable circumstances for exchange and does not use language commonly used in other regulations. The conditions under which it is appropriate to exchange health information are specified elsewhere and should not be included in the Governance regulation.
2. Trust fabric should be decoupled from the transport mechanisms. Transport standards should not be specified in this Governance regulation. However, the Governance regulation should require transparency with regard to the transport protocols that an NVE supports, and how it supports those protocols.

General Comment: An NVE’s implementation of its transport specifications (for example the Direct specification) should be certified through a process that is separate from the overall NVE validation process. The RFI states that “In our use of the term validation throughout this document, we mean it to encompass both accreditation and certification.” We think it would be a mistake to include certification as part of the validation process. While acknowledging that the use of certified technology may be a consideration in validating an NVE, the actual certification of that technology should be accomplished through a separate process (though both processes may be part of a single governance model).

Question 46: If a secure “RESTful” transport specification is developed during the course of this rulemaking, should we also propose it as a way of demonstrating compliance with this CTE?

See response to **question 45**

Question 47: Are the technical specifications (i.e., Domain Name System (DNS) and the

Lightweight Directory Access Protocol (LDAP)) appropriate and sufficient for enabling easy location of organizational certificates? Are there other specifications that we should also consider?

Yes, these specifications are appropriate for use, but we do not think the Governance regulation should specify these approaches as exclusive. There may be other ways to discover certificates, and we do not believe a Governance regulation should specify protocols for certificate discovery. We believe questions 45-47 are at a much more granular level than is appropriate for a Governance regulation.

Question 48: Should this CTE require all participants engaged in planned electronic exchange to obtain an organizational (or group) digital certificate consistent with the policies of the Federal Bridge?

This is a policy question and will be looked at by the Privacy and Security Tiger Team.

Discussion

Mostashari observed that he heard two policy principles in Baker's comments: do not specify the specification standards simply to be transparent and standards setting should not be conducted at the governance level. Regarding the former, he doubted that this is adequate to ensure progress. And if governance does not set standards, what would be the point of governance? Baker responded that in order to make progress, it may be better to validate an organization that already has certified technology. For example, one could determine that an organization uses certified EHR technology and then the validation body would examine its consistency with organizational policies. Mostashari wondered how, if not by regulation, standards would be set.

Malec purported to have an answer. He said that two things have to happen. The certification criteria should be unambiguous and enable plug and play. There should be mechanisms to change and replace standards and the implementation guide because they will change more rapidly than regulations. He asked about the feasibility of having a sub-regulation agency to do some of this work. (Writer's note: There were several references throughout the meeting to an e-mail sent by Malec prior to the meeting on this topic. The writer did not have access to the message and it is not referenced in the meeting materials.) Baker asked Mostashari whether he envisioned that EHR standards would continue to be regulated as they are currently. Halamka noted that similar to the EHR certification, attestation could replace validation. Mostashari continued to press for how consensus could emerge around evolving standards for CTEs without inclusion in governance. Baker suggested that the standards could be added to the EHR regulatory process and the same mechanisms used. The 2-year frequency would be adequate. Rishel gave his perspective. ONC has carved out a role of coordination of standards with gap filling by the S & I Framework and now prefers to have the work carried forward with CTEs and NVEs. Although there is a close link between CTE interoperability and EHR certification, accreditation of NVEs and conformance with Meaningful Use reporting are not really parallel. Accreditation involves direct examination of an organization, in part from third party information. That process has yet to be worked out. ONC needs to establish a parallel process with one organization tightly coordinated with regulation to create CTEs and another organization that translates these requirements into examination of NVEs. Walker said that the face validity of the process would be enhanced by emphasizing its similarity to Meaningful Use certification. Baker pointed out that many of the Meaningful Use objectives are based on attestation.

Walter Suarez pointed out the excessive back and forth of the comments. More definition is needed. He described four levels. The top level consists of policy standards and specific cases. The second level is made up of technical standards and implementation specifications. The third is certification criteria and the fourth is testing procedures for levels one through three. The third and fourth levels have yet to be defined. He suggested mapping the four levels for each CTE and level of regulation.

Chairperson Perlin announced that the agenda must be moved.

7. Preliminary Comments on RFI from Privacy & Security Workgroup

Dixie Baker, Chair, begin by saying that much of her report is a repeat of the two previous agenda topics. She emphasized that the preliminary comments have yet to be approved by the workgroup members. She reported that in addition to the questions assigned to the workgroup, members had addressed the question on the voluntary process. Her slides listed the conditions, questions assigned to the workgroup and the preliminary comments. She read them.

Question 22: Are there HIPAA Security Rule implementation specifications that should not be required of entities that facilitate electronic exchange? If so, which ones and why?

- The integrity of the validation process, and ongoing oversight and policy enforcement, are critical to the success of the voluntary approach.

Baker also showed slides that the group had prepared on the HIPAA addressable implementation standards and their applicability to the topic. Suarez noted that all are actually policies. Baker asked members to inform her of any feedback.

Discussion

Halamka said that he heard from Baker's report that creating a whole new structure is not necessary. Transport protocols should not have different policy governance. Baker and Rishel disagreed on transport protocols. Mostashari suggested that different use cases and architecture imply different policy. McCallie commented that a modular approach with vertical layers may be appropriate. Kelly Hall wondered whether ignoring technical standards would make change more difficult. Baker said that she was actually recommending more standards. Suarez cautioned against requiring standards that are not yet mature. Mostashari repeated that the RFI is based on moving ahead with what is known now and leaving room for innovation. Halamka summarized the discussion, which he characterized as having been carried out with passion: parse the CTEs into a policy chunk and treat them in a way similar to attestation and a standards chunk that can be dealt with very specifically. A modular approach may be appropriate depending on the NVE's services.

8. ONC Updates

Query Health

Rich Elmore, ONC, presented his update accompanied by extensive slides that depicted how Query Health is intended to work. It is a community of participants that voluntarily agree to interact with each other. There will be many networks; requestors and responders may participate in multiple networks. He described two levels of standards: query envelope and policy requirements; and query, data and results requirements. Query envelope and policy requirements are applicable to any distributed query. The query envelope is query and content agnostic. The metadata facilitate privacy per the guidance from HITPC and use RESTful Interface specification to integrate RI natively. The query, data and results requirements are applicable to

clinical data sources (e.g., EHRs, HIEs, etc.). Health Quality Measure Format (HQMF) was modified to support the needs for dynamic population queries: It offers several advantages for queries, including avoidance of the need for another standard. It is secure, works across diverse platforms, is less costly and speedier. The clinical element data dictionary is quite extensive and concept mapping is in process. Several pilot projects are underway.

Elmore invited Michael Buck, Director, Primary Care Information Project, NYC DPH and Query Health Clinical Work Group Leader, to describe his pilot. Buck said that the health department had developed proprietary EHR applications for data collection. To get full coverage of NYC, generic standards for application are needed. Participating in validation of the use of Query Health provides that opportunity. The Regional Information Organizations will be involved through contractual arrangements for data aggregation. Both in- and out-patient populations will be covered. Eventually, maps will be produced to inform intervention efforts.

Perlin announced that due to the extended discussions of the RFI, the agenda would move to item #9. The S&I Initiative item was tabled until the next meeting. John Feikema, ONC, announced that Elmore's exemplary work for ONC was drawing to a close. Perlin asked Deering to ensure that the record show the HITSC's recognition and appreciation of Elmore's work.

Action item #2: Chairperson Perlin on behalf of the HIPSC stated his recognition and appreciation for Rich Elmore's work.

S&I Initiative on Long-Term and Post-Acute Care

Postponed until June meeting

9. Report and Recommendations from Clinical Quality Workgroup

Jim Walker, Chair, reminded the members that two tiger teams had been formed, one on essential elements and the other on value sets. The former has not yet completed its work. The Value Set Tiger Team developed a very narrow set of recommendations intended to facilitate stage 2 value set delivery and consumption. Walker read the recommendations, which had also been distributed to members in advance of the meeting:

Value Set Recommendations

Recommendation 1: Establish NLM as a single authority for the validation of value sets used in Stage 2 quality measures. NLM should serve as a single source of truth for MU2 value sets, and should publish periodic updates to reflect changes within the underlying vocabularies and/or changes made by value set stewards. ONC should coordinate with other agencies, value set stewards, and consensus organizations as needed for value set hosting and serving/delivery. NLM will cross-check the accuracy of Stage 2 Clinical Quality Measure value sets by comparing value set codes and descriptors against appropriate source vocabularies to assess value set validity, and will suggest edits to value set stewards to ensure the validity of vocabulary codes, names, and vocabulary system version.

Recommendation 2: ONC should expedite recommendations of the Implementation

Workgroup (Jan 2012) and Vocabulary Task Force (April 2010) related to establishment of a publicly available value set repository.

Recommendation 3: The value set repository established by NLM should build upon the IHE Sharing Value Sets (SVS) profile for storing and serving value sets, and incorporate Common Terminology Service 2 (CTS2) methods for managing vocabularies referenced by value sets.

Recommendation 4: Establish a web service for human and machine consumption of Meaningful Use 2 value sets. Consider NLM, AHRQ, or CDC as the Internet host for validated value sets. Provide output in commonly used formats, e.g., tab-delimited, spreadsheet or XML formats, suitable for import into SQL tables, and web service delivery. Support the creation of web-based views based on quality measure and value set names and numerical identifiers, QDM Category, code systems & code system versions used.

Discussion

Perlin asked members to keep their comments short. He requested that any opposition or modification requests be voiced.

Malec requested that insofar as one of the recommendations was being made for the third time, ONC be asked to report at date certain on the status of the recommendation. Walker and others agreed. Jacob Reider, ONC, said that he would be happy to give feedback. Perlin declared the value set recommendations accepted for submission to ONC.

Action item #3: Perlin declared that the HIPSC approved the four value set recommendation submitted by the Clinical Quality Workgroup with the addition that ONC be asked to report on the status of recommendation #3.

10. Update on Standards Vocabulary Developments

Betsy Humphreys, National Library of Medicine (NLM), reported that NLM staff has been working with ONC on vocabularies.

SNOMED CT to ICD-10-CM mapping is on track. The Implementation Guide for IMAGIC was published in April. ICD-9-CM to SNOMED CT mapping is 90% of use based on 2009 CMS data. This will provide aid for one-time transition to the use of SNOMED CT in the problem list

Upcoming projects include SNOMED CT Expansion for Devices and SNOMED CT Expansion for Dentistry. A number of contracts are underway to accomplish these efforts.

Discussion

Kelly Hall asked whether, in accordance with the “how do I compare” principle, Query Health will enable patients to compare their care with national data. She asked that the patient not be neglected in Query Health.

Halamka pointed out the need to agree on nomenclature in medicine. Humphreys said that NLM is working on it. Staff is discussing LOINC and SNOMED for radiology. Two radiology vocabularies may be required.

Perlin announced that the next meeting will start with the long term care update. Halamka referred to Malek’s nice summary of the discussions of the RFI recommendation.

11. Public Comment

Carol Bickford, American Nurses Association, asked ONC to update the glossary with the new acronyms.

SUMMARY OF ACTION ITEMS:

Action item #1: Chairperson Perlin declared the minutes of the April 2012 meeting approved with no changes.

Action item #2: Chairperson Perlin on behalf of the HIPSC stated his recognition and appreciation for Rich Elmore's work.

Action item #3: Perlin declared that the HIPSC approved the four value set recommendation submitted by the Clinical Quality Workgroup with the addition that ONC be asked to report DATE CERTAIN NOT STATED on the status of recommendation #3.

Meeting Materials:

Agenda

Summary of April meeting

Presentation slides