Health Information Technology Standards Committee

DRAFT

Summary of the August 17, 2011, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants the 28th meeting of the Health Information Technology Standards Committee (HITSC), which was conducted via telephone. She reminded the participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a summary of the meeting would be available online. She conducted roll call, and turned the meeting over to HITSC Chair Jonathan Perlin.

2. Opening Remarks

Perlin thanked ONC staff and Committee members for their dedication and efforts to date. He noted that virtual meetings require closer attention than when the Committee is together, and asked for everyone's support in making this an effective meeting.

> **Action Item #1:** The Committee approved by consensus the minutes from the July 20, 2011 HITSC meeting.

3. Review of the Agenda

HITSC Co-Chair John Halamka noted that during a conference held the day before this HITSC meeting, National Coordinator for HIT Farzad Mostashari reported that in some capacity over the last 2 years, this Committee has met on an average of every other day. Halamka characterized the HITSC as the hardest working federal advisory committee in history and noted that this meeting may be the group's most important. The Committee has achieved something that many have been working on for a decade. As the Committee proceeds through the meeting's agenda, it will, for the first time, be declaring true single standards and single implementation guides for each domain, and a clear path forward for all meaningful use Stage 1 and 2 standards that are necessary.

Halamka reviewed each of the agenda items, and said that in summary, if the Committee is successful in achieving consensus on the recommendations to be presented, this will be the day that parsimony was achieved.

4. Clinical Quality Workgroup and Vocabulary Task Force Recommendations

Halamka introduced this discussion by noting that the Task Force has sufficiently reassured him that the Committee's historical recommendations have been incorporated into its current recommendations. The Systemized Nomenclature of Medicine (SNOMED), RxNorm, and

Logical Observation Identifiers Names and Codes (LOINC) have now incorporated multiple previously recommended standards.

Vocabulary Task Force Chair Jamie Ferguson noted that the group has held approximately 10 meetings over the last 2 months. He reviewed the scope of the team's work as well as the foundational concepts that guided their efforts (these fall in the areas of measures development, HIT certification, meaningful use, and interim transition plans). Next month, the Task Force will present an initial set of recommendations for transition plans that will make it possible for users to move from the existing state of vocabulary usage to the recommended vocabularies and code sets. The Task Force is asking for Committee approval on the long-term target so that it can then set a direction with transition plans on a case-by-case basis as needed.

Ferguson then presented the recommended code sets in the areas of adverse drug effect, patient characteristics, communication, condition/diagnosis/problem, device, non-laboratory diagnostic study, encounter–"patient-professional interaction," patient experience, family history, functional status, health record components, intervention, adverse effect other than allergy, laboratory tests, medication, physical exam, patient preference, procedure, risk evaluation, substance, symptom, system resources, and transfer. Ferguson indicated that he believes transition plans will be required in six of the areas. The Task Force has scheduled meetings to develop a plan for those transitions, and in some cases it will be able to develop specific recommendations before the next HITSC meeting on September 28, 2011.

There has been discussion about incorporating these same vocabularies into the certification criteria for internal EHR functions, to make it easier for hospitals and eligible professionals to adopt these code sets. Ferguson said he would like to hear some discussion on that topic, but clarified that today's recommendations are only for the purposes of external quality reporting and testing to produce quality reports.

Discussion

- Wes Rishel asked whether it is anticipated that all of the mechanisms and funding are in place to produce some appropriate format similar to the formats that are produced for the concepts themselves. Will this be published as a concept network rather than a series of tables in PDF format? Vocabulary Task Force Co-Chair Betsy Humphreys said that this issue is under active discussion between the ONC, National Library of Medicine (NLM), and others. The intent is that these will be available in useful forms, although they are not ready today.

- With regard to the timing of these recommendations, Halamka asked whether all of this work will be within a timeframe that would ultimately have these standards being widely used in 2014. Ferguson commented that this concern is exactly why the Task Force sees the need for transition plans for some of these items. There are a number of new or retooled measures that already exist using these recommended code sets, but because of other work that has already been done and the fact that some of the 2010 measures use alternative vocabularies, there will be some transition needed. However, only six of the 23 domains need transition plans, so the large majority of them could be using these recommended vocabularies in 2013.

- Carol Diamond asked what the process will be in order for the Task Force to be confident that everything necessary to implement these standards is available and in fact is implementable, having survived field testing. Floyd Eisenberg explained that Centers for Medicare and Medicaid Services (CMS) and ONC have projects (either planned or in progress) to address this. Ferguson pointed out that with the possible of exception of the Centers for Disease Control and Prevention (CDC) PHIN Vocabulary Access and Distribution System (PHIN VADS), everything that the Task Force is recommending is already in use in meaningful use Stage 1 quality measures.

- David McCallie asked about the tight coupling between LOINC and SNOMED, and how that relationship will be managed at the high level. Humphreys said that there is an ongoing series of discussions about the establishment of a specific relationship between the two. No total merger is expected in the immediate future, but there will be a closer relationship.

- In response to a question about whether SNOMED answers will be standalone or whether they will require the LOINC question for interpretation, Stan Huff said that in most situations, to understand the meaning that is being expressed, it is necessary to understand context of the question. The name of a disease is the name of a disease, but did the condition happen as an adverse reaction to a drug? The context of the question must be present.

- In response to another question, Ferguson explained that the problem list is one area where the Task Force can look at whether this vocabulary issue could usefully be expanded. If, for quality measure purposes, one is required to represent the problem list in SNOMED CT, then how best should one do that? What would make it easiest for end users to meet that quality reporting requirement? Should certification be used to test the ability of a problem list to be captured with the use of SNOMED CT or not?

- Halamka explained that this work is about quality measures. Another way to consider these vocabulary measures is for use in data transfers. The most controversial question is, should these vocabularies be used natively? Ferguson stressed that the question is, should they be able to be used natively; the Task Force would not be mandating it. Halamka said he would be happy to use these for quality measures, but it would be a struggle to convert existing code sets in all of his institution's applications to such new structures in the near term. This is the direction he would like to move towards eventually, however.

- Wes Rishel noted that he is mindful of the lessons they learned with regard to implementing LOINC, specifically that the balancing of the need for precision with simplicity was both a barrier to the acceptance of LOINC and a cause of error in implementing it. He does not know exactly how that lesson transfers here. He echoed Carol Diamond's concern, saying that certification is step 1 towards getting these quality measures implemented. Step two is using them in order to meet meaningful use criteria, and this is the bigger step. He recommended that they make the process of development very public, and look for continued feedback on the implementation that has happened in stage 1 during the time when people are actually reporting quality measures as opposed to attesting.

- Halamka said that in the short term, most EHRs will not natively use these vocabularies, but will map to the quality measures expressed in the vocabularies they have discussed today. That will work, except that there will be some loss of information fidelity. They can only move as fast as the industry can implement.

- Dixie Baker asked whether there will be an effort to align these mappings with those that will be required for the ICD10 transition. Humphreys said that the main goal in all this mapping work is to be ensure that there are not duplicate mappings created. They are attempting to have a unified approach, with major groups like Kaiser working together and sharing resources. They hope not to hear that resources are being expended on duplicate efforts, or worse, on contradictory mapping work.

- Rishel pointed out that the mapping problem most people will encounter is between their own ad hoc system of codes and the standard system of codes. There is no potential for making a standard mapping available in this case. He expects that this is an opportunity for industry to develop tools for creating mappings. It would be an interesting agenda item at some time to examine where the industry is in that regard, and what can be done in the public policy sphere to ensure the availability of those tools.

- Halamka pointed out the need for mapping between standard proprietary sets of commercially available codes and SNOMED, etc.

- Carol Diamond pressed the point that the HITSC and ONC need to consider a glide path for putting forth requirements that have not been tested and validated before they can be mandated. She said they need a proactive process whereby there is some testing of implementation in a diverse set of environments, and not just by a small handful of entities that may be well adept at implementing complicated standards.

- Rishel added that it is also crucial to actively seek and monitor industry experience in implementing these standards as they develop the transition plans. Halamka concurred, and said it would make sense for the Certification Workgroup to do that monitoring.

- Judy Murphy referred to the ongoing tracking of implementation experiences. In the past it has been more of an episodic tracking, and this would be a more iterative, open ability to give comments all of the time. Diamond concurred, and said she is envisioning a proactive process even before they make these mandatory requirements.

- The Committee accepted the Clinical Quality Workgroup/Vocabulary Task Force recommendations with the caveats that the Task Force will actively seek input on industry experience, and that the Certification Workgroup will carry out monitoring. It was noted that the Committee was not voting on an expansion of scope for these recommendations.

> **Action Item #2:** The Committee accepted the Clinical Quality Workgroup/Vocabulary Task Force recommendations with two caveats: (1) the Task Force will actively seek input on industry experience, and (2) the Certification Workgroup will carry out monitoring.

5. Standards Summer Camp

Halamka introduced this series of presentations, noting that the groups are proceeding through the activities that were outlined in April, exactly as planned.

Patient Matching Power Team Update

Patient Matching Power Team lead Marc Overhage reminded the group that last month, the HITSC offered helpful feedback and discussion to the Team, and with the document being presented today, the Team has attempted to incorporate that input. He highlighted and opened up for discussion two areas that were the most contentious and where they could use the most input.

Recommendation one is the first area of difficulty. The Team tried to base its recommendation on some reasonable assumptions about minimal levels of sensitivity and specificity around which they might expect policy to be based. Simply using first name, last name, and date of birth, even when the data are perfect, does not achieve those minimal levels, and adding Zip code in does not add enough to get them to where they need to be based on the available literature and experience. Rather than being proscriptive, the Team was trying to provide guidance about what the tradeoffs are in terms of achieving appropriate specificity for a use case.

The second area of discussion relates to the Team's last recommendation, where the group spent a fair amount of time trying to come up with a good way to characterize the matching process so that the requestor could be given some information that would give him or her faith in the matching process. The Team felt as though it did not come up with very good potential metrics—the best they could do was to suggest that the provider of the matching service should offer a contact person who would be accountable for being able to answer questions and describe the matching process. The Team may want to add to that a basic checklist of quality approaches that have been applied to the data, although there are challenges to doing that in a large distributed environment, because those might be quite diverse.

Discussion

- Carol Diamond explained that the group cannot optimize a matching algorithm at the national level. This group's job is to describe the level of sensitivity and specificity that is necessary, and to provide standards recommendations across the whole set of possible fields. People will need to use a variety of fields, so why not recommend standards for any of the fields that might be used for optimizing?

- It was suggested that the Patient Matching Power Team converge this work with the notice of proposed rulemaking (NPRM) metadata work.

- David McCallie pointed out that the more they specify, the more accuracy they will attain. The tradeoff is, when do they feel they have crossed into specifying too much information, in other words, putting privacy at risk? That can be left to a local decision, but local decisions have national implications because people move from one location to another. Have they

gone far enough in specifying the tradeoffs in increased accuracy and perceived risk of security loss?

- Wes Rishel commented that the balance between sensitivity and specificity is going to continue to be a policy issue for a long time. The best they can do is be sure that whatever is decided for policy in a specific place can be implemented interoperably, and that the decision makers have the best information.

- In response to a question from Dixie Baker, McCallie explained that the Team did allow for the possibility of a voluntary health identifier number. However, the reality is that this does not exist, so it cannot be used today. If it is allowed, none of the historical data will include it, and its penetration will take considerable time.

- Chris Chute pointed out that if the intent is to provide guidance so that implementers know what fields to start managing, then an anticipatory field, like one for the voluntary health identifier, would logically be a very important piece of that guidance.

- Marc Overhage noted that the Team did include a voluntary identifier as a potential piece of information to use in matching. He believes that the clinical document architecture (CDA) R2 header format accommodates a variety of specific identifiers. He asked what further information they could add to accommodate this possibility. Halamka suggested recognizing the helpfulness of a social security number, and acknowledging that, likewise, perhaps a health care identifier would be helpful.

- Halamka closed the discussion by pointing out that the Committee has heard that this Team could use some guidance, and encouraging HITSC members to provide the feedback that the group is seeking. Next month, the Patient Matching Power Team will present its recommendations.

Surveillance Implementation Guide Power Team Recommendations

Chris Chute presented the conclusions of the Surveillance Implementation Guide Power Team's activities. For electronic lab reporting, the team recommends that HL7 2.5.1 continue to be used. Most immunization reporting is done by proprietary reporting systems. There is metadata and information in HL7 2.5.1 that is not in 2.3.1, so the consensus was to recommend restricting it to 2.5.1 and its associated implementation guide. For syndromic surveillance, from a technical perspective, there were less compelling reasons to pick 2.5.1, but they liked the elegance of consistency and the Team wanted to avoid having a mixed set of recommendations. Given the functional characteristics being equivalent, they opted for 2.5.1 for syndromic surveillance.

There is a caveat related to implementation guides. There will be an implementation guide for hospitals published imminently; however, eligible providers are unlikely to have an implementation guide developed in time for meaningful use Stage 2. Therefore, the core element for eligible providers in the absence of an implementation guide should be carefully considered, and perhaps not recommended.

The scope of public health reporting may transcend the capabilities of 2.5.1. It is consistent with the capability of most providers, but the inertia is going to rest with the recipients, because the public health infrastructure generally does not have the ability to receive the information. Therefore, the Team is not making a recommendation in this area, except to be mindful of the evolution over time of public health reporting around a CDA-type architecture. For now, 2.5.1 is the single preferred standard for health reporting surveillance.

> **Action Item #3:** The Committee agreed by consensus to accept the recommendations of the Surveillance Implementation Guide Power Team.

NwHIN Power Team Update

NwHIN Power Team lead Dixie Baker offered an update of the group's work, reminding the Committee of the team's charge, and reviewing the specifications that were included for NwHIN and the Direct Project. She described the process used by the Team to select the specifications. Then, she presented the Team's preliminary results in a table highlighting the scores of the various specifications considered, based on the selection process that she described.

Discussion

- Halamka pointed out that the Team has been looking at push and pull mechanisms for delivering data, but there is also the notion of delivering a view of data, as in the Blue Button. This is not sending files, but simply providing data views. He said it may be interesting to consider this in ongoing work.

- David McCallie, speaking as a member of the NwHIN Power Team, commented that one of their debates has been around the questions they were being asked, and more importantly, the questions they were not being asked. The Team has a list of building blocks, but to construct a building, one also needs a specific architecture. These building blocks would work well for some purposes, but not for others. They have not addressed which of these building blocks fits bets for a given architecture—this is outside the team's scope, but it is an important question.

- Baker explained that this work will help inform ONC's decisions about where to invest in pilots and further standards development. Halamka clarified that as they constrain the field of standards, they will arrive at a sense of what needs to be piloted based on maturity, and what does not yet exist.

6. S&I Framework Update

Jitin Asnaani introduced this series of discussions, noting that in the spirit of incrementalism, each initiative focuses narrowly on a specific challenge. This is a final update on the community findings of the Standards and Interoperability (S&I) projects so far. Each initiative community leader discussed their project's findings, followed by a conversation about how this work can help with standards goals.

Asnaani walked the group through the Certificate Interoperability findings, summarized as follows:

- There is a gap in federal Public Key Infrastructure (PKI) policy to address identity validation for organizations requesting server certificates.
- In light of this, the initiative evaluated options for ONC to provide support to the industry

The following actions were suggested for the HITSC:

- Monitor progress of the General Services Administration (GSA) development of policies for organizational certificates.
- Confirm that interim certificate practices align with anticipated federal bridge certification authority (FBCA) policies.
- Review the transition plan for migration to FBCA organizational certificates.
- Monitor the development of a Health Bridge.

John Donnelley and Russell Leftwich discussed the Transitions of Care (ToC) Initiative. The key consensus findings were:

- The CDA consolidation (HL7 CDA Release 2) ballot results are the best standard to use in support of meaningful use requirements.
- Tooling, testing, and educational resources will ease implementation.
- The Transitions of Care clinical information model (CIM) provides clinical perspective for care transitions and maps to HL7 CDA Release 2.

It was suggested that HITSC consider the following actions:

- Agree on a standard for care transitions for meaningful use Stage 2.
- Recommend EHR certification criteria for incorporation and usage of structured care transitions documents.

Hans Buitendijk and Ken McCaslin presented the key consensus findings of the Lab Results Interface Initiative, summarized as follows:

- The new Lab Results Interface implementation guides leverage profiles to simultaneously provide constraints while allowing for flexibility and higher interoperability.
- LOINC should be used for observation identifiers and SNOMED CT should be used for reporting of appropriate lab results.
- Use of SNOMED for reporting specimen information and UCUM for units of measure are likely, but each requires piloting for consensus.
  - In the near-term, textual units of measure should be transmitted in correct observation segments.

They suggested the following actions for the Committee:

- Agree on a lab results reporting standard for ambulatory primary care to support meaningful use.
- Recommend vocabularies or near-term guidance for observation identifiers, lab results, specimen information, and units of measure.

Bob Dieterle presented the following key findings from the Provider Directories Initiative:

- Certificate Discovery for Direct Project:
  - A hybrid DNS/LDAP solution allows a greater number of implementers to effectively enable certificate discovery and management.
  - Implementers have volunteered to expend the resources to build this solution into the Direct Project RI and to conduct pilots.
- Query for electronic services (including the electronic address):
  - Standards to support queries to provider directories have limited deployment.
  - Broader implementation experience is needed to allow an evidence-based approach to standards selection.

He suggested the following actions for the HITSC:

- Agree on an approach (including additional data required and timetable) for recommending: (1) standards for certificate discovery for Direct Project participants, and (2) provider directory query standard(s)

Jitin Asnaani pointed out that in these presentations, they called out the findings of more than 7 months of work done by about 300 people.

Discussion

- Dixie Baker commended the work of those who developed the S&I Framework and said she personally concurs with their findings on certificate interoperability. They are working with the GSA to resolve issues around the fact that the federal government has no policies with respect to governing an authenticating organization's identity. They recently learned that the federal government is behind in its enforcement of requiring that certificates be issued in cross-certified organizations. The Direct Project Rules of the Road already specified the policies they recommend, and she would like to suggest that this be expanded to apply to the entire nationwide NwHIN, not just Direct.

- David McCallie cautioned that operationalizing a bridge is a step that goes far beyond the mere issuance of bridge certificates. It may take longer than 6-9 months. Meanwhile, most agencies seem to be using multiple routes that adhere to a common policy, and he thinks this is consistent with the recommendations.

- Wes Rishel referenced a comment that Dixie Baker made recommending that the approach being adopted by the Direct Rules of the Road be applied to Connect as well. He asked for clarification on how that might happen. Baker said she was referring to the slide saying that in the interim, the NwHIN—including Direct—should use certificates that align with the

Federal PKI policies. She agrees with that recommendation, but she does not know what the exchange community has in place to ensure that they, too, are aligned with the Federal PKI policies. As they try to move towards a single health information network (HIN), it would be worthwhile to have a single body looking at policy for both.

- McCallie indicated that the group has received some inconsistent information on Exchange's use of the bridge. Some work is needed to reconcile these issues.

- With regard to the list of priorities, medications, and allergies in transitions of care, Jamie Ferguson said that they have just had a large discussion on standardizing vocabularies for use in quality measures. All of the same external reporting requirements must be included in standardized vocabularies for quality reporting, and reconciliation is easier if the drugs are described in the same way. He asked whether they have considered using the same standards for exchange as for external quality reporting. Russ Leftwich indicated that this discussion needs to occur. The group worked with the concept that it would make sense to have the same vocabularies used in all aspects of data exchange.

- John Donnelley commented that they have not taken on as a specific charge the harmonization of the two data needs, but he did not see any disconnects or conflicts between the vocabulary information that was presented earlier and the CDA consolidation ballot work.

- Stan Huff said there is a national and international initiative getting underway around clinical information modeling that would overlap with this work. He asked about opportunities in the future to use that work rather than have all of the work done within the S&I Framework without any international coordination.

- Carol Diamond raised a process issue regarding the transfers of care work. In the Wiki, reference was made to the fact that there were not enough volunteers to support the use of a new standard. In accepting these recommendations, if there are less than 10 participants, or if participants acknowledge that they did not get enough volunteer support for a robust discussion, it would be helpful to acknowledge that fact. They can then go back and try to get that discussion accomplished rather than taking a recommendation that may not have enjoyed sufficient discourse.

- Wes Rishel referred to slides 13 and 15, and indicated that use of the term "optional" may not be appropriate. Slide 13 refers to human-readable unstructured text, without a clear statement of what that means as a requirement for those sending information or receiving it. Slide 15 discusses a library of harmonized templates. What is the implication on a product developer and on an organization using a product? Do they have to be prepared to receive all of the templates? To send all of them? Or is it only in the circumstance when someone chooses a specific template that someone else likes that interoperability occurs? He said that in all of the efforts that they have seen, the pilot and early adopter efforts around accepting CDAs into an EHR have shown that it is an extremely difficult process to implement. That is especially true for problem lists and allergies, and he urged that the group be very careful and take into account the actual workflow necessary at the point of acceptance.

- Rishel also commented that he strongly supports the clinical information modeling work that Stan Huff referred to earlier. That and Green CDA are both in a stage that they are not appropriate for consideration in meaningful use Stage 2, but they each have a reservoir of intellectual property that could make them move faster than has been seen in the past.

7. Implementation Workgroup Update

Implementation Workgroup Co-chair Liz Johnson reviewed the group's work plan and timeline. They recognize that the practicality and usability of both criteria and standards is critical, and are taking that into consideration in their work. The Workgroup had more than 100 pages of certification survey results to share with the Committee; Johnson presented some of the high-level results, noting that all comments have been or are being given consideration.

A wide range of respondents have indicated that the following points were successful:

- Authorized testing and certification bodies (ATCBs) provided guidance and processes that were helpful.
- Choices in testing and certification bodies should continue.
- Use of remote testing capabilities was useful.
- Consistency of standard National Institute of Standards and Technology (NIST) testing procedures.
- Addition of modular certification.
- Ability to seek site certification.
- Distribution of information including ability to access via web, blogs, FAQs.

Global suggestions for improvement include:

- Lack of clear guidance to ATCBs led to inconsistency.
- Certification criteria are not clear and lack sufficient details.
- Certification criteria did not address clinical specialties/ancillary activities.
- FAQs were issued late and not cross referenced.
- Modular versus complete EHR requirements are confusing.
- Debate over certification criteria focus: What are they looking for?
  - Interdisciplinary usability.
  - Work flow centric (using meaningful workflows).
  - Alignment of results and outcomes with meaningful use objectives.
- No stated plan for certifying new releases of EHRs .
- Difficult to discern which products combine to achieve a complete EHR.
- Lack of assurance of interoperability between certified products.

Johnson then presented comments on a number of specific criteria, such as public health surveillance and reporting, exchange of information method, security and privacy, etc.

Workgroup Co-Chair Judy Murphy then presented the Workgroup's certification recommendations for meaningful use Stage 2, as follows:

- Create a grid that shows the standards, certification criteria, testing methodology, and implementation guidance for each of the Stage 2 meaningful use measures, including the quality measures.
- Launch a unified HHS Web site that serves as the "single source of truth" for CMS' meaningful use and ONC's certification programs.
- Establish a clear process to manage updates to specifications for meaningful use measures and quality measures.
    - Include version numbers and release notes for all updates so users can easily identify the most recent info and clearly understand what has changed since the last update.
- Indicate whether updates are mandatory or optional.

Murphy then presented the group's key action items, which include a complete analysis of the survey findings and a project with ONC to create a grid for meaningful use Stage 2.

Discussion

- Dixie Baker noted that she has asked for a timeline indicating when ONC requires input for standards and criteria for meaningful use Stage 2 and repeated that request. She expressed concern that the group will be informed that the ONC needs all of their recommendations for standards and certification criteria on a very short timeline and asked for guidance on this issue.

8. Public Comment

Carol Bickford of the American Nurses Association commented that in relation to the matching discussion, she strongly encourages being proactive in including the additional field necessary to allow a unique health identifier. With regard to the vocabulary discussion, she noted that it would be beneficial to have resources or a central office or entity to help them move forward on the mapping strategies.

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee approved by consensus the minutes from the July 20, 2011 HITSC meeting.

Action Item #2: The Committee accepted the Clinical Quality Workgroup/Vocabulary Task Force recommendations with two caveats: (1) the Task Force will actively seek input on industry experience, and (2) the Certification Workgroup will carry out monitoring.

Action Item #3: The Committee agreed by consensus to accept the recommendations of the Surveillance Implementation Guide Power Team.