

Health Information Technology Standards Committee

DRAFT

Summary of the October 27, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 18th meeting of the Health Information Technology Standards Committee (HITSC). She reminded participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments. She conducted roll call, and turned the meeting over to HITSC Co-Chair John Halamka.

2. Opening Comments and Review of the Agenda

John Halamka indicated that National Coordinator for Health IT David Blumenthal has reported that the Office will be proceeding carefully with Stages 2 and 3 of meaningful use, and that these will not be finalized until there is a careful review of the success of Stage 1. It is hoped that there is much more time to prepare Stages 2 and 3, and this meeting represents an opportunity to begin discussion of some of the major topics for Stages 2 and 3.

John Halamka reviewed the agenda. Committee members then approved the minutes from the September HITSC meeting.

Action Item #1: Minutes from the last HITSC meeting, held on September 21, 2010, were approved by consensus.

3. Vocabulary Task Force Update

Vocabulary Task Force Chair Jamie Ferguson noted that the group is working towards a set of recommendations to bring forward to the Committee on how to manage intellectual property issues for meaningful use related to the vocabularies. The Task Force hopes to discover how to help make those issues be more easily managed by eligible professionals and hospitals and any other organizations that are the intended recipients of the meaningful use incentives. They are working to better understand the current landscape of who pays for what, how intellectual property issues are managed by the same entities for other purposes, and what is different about meaningful use, to develop a set of recommendations that specifically relate to the content sets for performance measures and quality measures related to meaningful use.

An analysis is currently underway of who pays for what standards today. What are the models that are being used? This also includes the use of vocabulary and the messaging standards such as those for the administrative simplification transactions.

The Task Force also is examining the coordination of measure sets. Previously, the group discussed the need for some central coordination of the standards that are used in the content sets

across different measures that are developed by different measure developers, to ensure that terms have the same meaning wherever they are used. Also, the group put forward the concept that there would be a primary organizing principle for the development of the content sets and the measures by domain.

John Halamka offered some examples of how intellectual property questions can become complicated and potentially cause barriers. Jamie Ferguson indicated that the Task Force has determined that it wants to explore two alternative models for making these issues simple for implementers. One is some form or perhaps multiple forms of a national license, paid by the government with potentially some cost recovery scheme on a fee for eligible professionals, hospitals, and other organizations in meaningful use. The second is an administrative model in which essentially an officer agency or contractor of the federal government essentially would administer licensing fees on behalf of the users of the intellectual property.

In a September hearing, members of the Task Force heard very clearly that although free is always better, providers generally are used to paying for standards. However, they want to have a simple, one-stop place to go so that they don't have to track their use of the different aspects of different intellectual property and determine who to pay, how much, and for what.

4. Implementation Workgroup

Implementation Workgroup Co-Chair Liz Johnson announced that two new members have joined the Implementation Workgroup: Tim Brooks from Emory University, and Mera Choi from the ONC.

The Workgroup proposes to have a panel hearing in January of 2011 on the subject of real-world experiences working with meaningful use. The group wants to ask eligible providers how their implementation experiences are going, and what issues they are experiencing in terms of barriers that this group could potentially assist with.

The Implementation Workgroup also wants to learn what kinds of experiences the certifying bodies are having, and its wants to examine the regional extension centers (RECs) and the state health information exchanges (HIEs). The group is attempting to cover the environment in terms of those who are contributing to the ability to meet implementation requirements. Workgroup members also will be exploring the possibility of merging this group with the HIT Policy Committee's (HITPC) Adoption Workgroup to collect implementation/adoption experiences.

The Implementation Workgroup intends to hold a 1.5-day hearing that will include panels discussing the following five topics: (1) the role of RECs in attaining meaningful use, (2) certification experiences, (3) early adopters of meaningful use seeking attestation in 2011 and guidance for future implementers, (4) meaningful use criteria, and (5) HIE.

In discussion, the following points were made:

- John Halamka reported hearing stories of some electronic health record (EHR) vendors that have had to create the wrong standards in their EHR for syndromic surveillance because the

wrong implementation guide was placed into the regulations. So for certification, they have created software that cannot possibly work. This is obviously a short-term problem, and there has been some debate within the ONC about how to correct this.

- John Halamka asked for clarification about the fact that the HITSC specified National Council for Prescription Drug Programs (NCPDP) 8.x or 10.x. The Committee did not specify an XML or EDI form, and then he heard that some vendors, when using some National Institute of Standards and Technology (NIST) test scripts, were told that they do not actually support the XML form on the test script. Therefore, people must certify to the EDI form. Kamie Roberts of NIST indicated that she would check on this.
- Walter Suarez suggested that the Committee increase the scope of the federal blog for people to submit questions and obtain many other perspectives focusing on meaningful use. In this way, they would receive a larger cross-cut than a four-person panel. He also suggested bringing in a group of state HIE coordinators to discuss efforts in their respective states.
- Kevin Hutchinson said that it is not the Workgroup's intent in the upcoming panel discussion on RECs to delve into business model issues. Rather, the panel will focus on how RECs are applying and supporting the efforts to get to meaningful use.
- Jim Walker suggested that there is a larger population that has less robust health IT functions that those who will probably be selected for the panels. It is important for the Workgroup to capture their experiences as well.
- In response to a comment from Chris Chute, Liz Johnson indicated that the ONC had been asked to provide a report card of data around progress towards implementation. It would be beneficial for the Office to share a template with the Committee, so that HITSC members can see what the report card will actually look like, and make sure that the work is in progress.

5. Meaningful Use Workgroup Update

Paul Tang reviewed the Workgroup's progress to date, beginning with how it moved through the Stage 1 recommendation process. He also discussed philosophical approaches to Stages 2 and 3, which include: (1) the positioning of Stage 2, (2) migration to outcomes, (3) patient engagement information sharing, and (4) deeming of external criteria.

In discussing the positioning of Stage 2, he explained that it could be seen as an incremental change over Stage 1 (which has the advantage of extending current implementation plans but the disadvantage of continuing the uncertainty for the market in terms of Stage 3). The positioning of Stage 2 also could be seen as a stepping stone to Stage 3 (carrying with it the advantage of establishing a roadmap and timeline). The HITPC asked whether the Workgroup could take both approaches. Paul Tang indicated that this would be possible, and that the Meaningful Use Workgroup intended for Stage 2 to be some manner of incremental change from Stage 1.

Paul Tang also discussed migration to outcomes and included the examples of drug interactions and readmission rates in order to illustrate the notion of outcomes orientation. Potential areas of

focus for the Meaningful Use Workgroup include: (1) set Stage 3 outcomes-based measures; (2) deem satisfaction of the process measures by achieving a threshold performance measure; (3) directly measure the benefits of HIT; (4) support value-based purchasing (to reduce dependence on process measures); (5) reduce the emphasis on the “how,” in favor of the “what,” to promote innovation; (6) reduce the burden of measuring structure and process, and (7) introduce outcomes orientation in Stage 2.

Regarding patient engagement and information sharing, Paul Tang commented that the entire notion is one that should be owed to the patients and caregivers. The Workgroup has also been discussing ways of meeting meaningful use criteria, other than simply the functional requirements of the software.

Paul Tang then discussed deeming of external certification. He suggested using external certification to deem satisfaction of specific meaningful use criteria. One hypothetical example is the question of whether satisfaction of meaningful use category 1 criteria (quality, safety, efficiency) satisfies the HIT component of professional maintenance of certification for medical boards. Additional guiding questions include: Are there multiple “tracks” for achieving meaningful use? Does achieving high performance on quality measures satisfy certain meaningful use categories?

The Meaningful Use Workgroup presented before the HITPC last week and obtained feedback. It will use that feedback as well as HITSC input to continue working on the individual criteria for Stages 2 and 3. Paul Tang presented the next milestones on the Workgroup’s calendar, and acknowledged that they are between “a rock and a hard place” in terms of timing. All parties involved want to have more time to prepare for Stages 2 and 3, but they also cannot ignore what is happening with Stage 1. There is also the matter of the clearance and proposed rulemaking processes that means that the final rule cannot be released with the 18-month lead time that was desirable. Every effort will be made to provide industry with enough signals to point them in the right direction, as they await the final rules from the Centers for Medicare and Medicaid Services (CMS).

In Committee discussion, the following points were made:

- John Halamka reported that he is hearing from industry that they need to understand the direction in which this work is proceeding. It would be very helpful to industry if this Committee could offer a general plan of the steps to Stage 3.
- Carol Diamond expressed hope that the HITSC could discuss the direction it appears to be moving in with regard to document creation and registries. As she has stated before, she does not know that they are going to get to all of the documents in use in health care without creating a lot of complexity.
- Jim Walker addressed process measures and outcome measures. He said that patient outcomes are the issue. The problem is that process measures are leading indicators, and outcome measures are lagging indicators. Even for the most effective therapies, it would take an average-sized hospital years to have enough patients to show a difference between a

hospital that did a perfect job and a hospital that did a bad job of that process measure. The Committee and ONC must nuance their understanding of process measures and outcome measures so that they do not lose the ability to measure the quality provided by small and even average-sized practices and hospitals. They are more likely to get to outcomes if they provide those smaller organizations with standard process measures that have been shown in validated studies to be linked to outcomes, and then update that when they find that some of those punitive or those process measures do not actually correlate with outcomes.

- Paul Tang indicated that the focus now is on the exchange standards from the HITSC, and the Meaningful Use Workgroup would like to obtain additional input on what they can be moving towards in Stage 2.
- It was noted that the HITSC could weigh in with a discussion of how to be more patient specific without a set of standards. This might include a discussion of SNOMED versus ICD. In 2013, it should be ICD-10, but will it be patient specific because of ICD-10, or does the answer lie in the clinical terminology of SNOMED?
- George Hripcsak suggested that meaningful use may create a market in which patients have a large amount of complex data and a third party helps them interpret it.
- Kevin Hutchinson emphasized that it should be made clear to the community where this Committee stands on the goal of being comprehensive in nature or minimalist in nature. Interested parties are waiting to see if the Policy and Standards Committees are going to create a type of comprehensive, all-encompassing document that will solve all of health care's problems, or if the Committees are simply trying to jump-start the process to get it moving in the right direction with a minimal set of standards.
- David Blumenthal commented that he hopes the perception is not that the Committees are defining a ceiling for what the industry can do or what any individual health care organization can do. The HITPC and HITSC hopefully will get HIT on a trajectory towards more and more comprehensive, sophisticated uses. He expressed hope that the industry will move far beyond what requirements are being set, and in fact, he sees that this is the case. Some organizations are at or beyond meaningful use already.
- Wes Rishel commented that an incentive is an incentive if the targeted party believes that, with diligence and investment, they can meet the incentive. When requirements are set with those policies that they cannot meet on their own, they require other people in the community to meet them. However, if there is no value-based purchasing or other economic tie between the elements, then there is the risk of making the incentive un-credible, which is detrimental for the overall program. This applies clearly to interoperability.
- Wes Rishel explained the tension between how much they want to emphasize measuring processes and how much they want to emphasize measuring results. The meaningful use goals will be an intermediate position. He asked if they are at risk of creating another set of guidance on what outcomes are important to physicians and hospitals, when those entities already have many different sets of guidance on this issue. Are they better to focus on

measures that demonstrate the enablement of IT under the incentives program, and measures that demonstrate the effectiveness of the hospital organization, IT, and other items?

- David McCallie discussed what he termed “preservation of causality.” They do not want to simplify the data to too many levels of abstraction because that will blur causality. It will cause loss of the information that is necessary to go back in time and identify what happened. They must be able to move the data to other places, and also preserve as much of the data as possible because they do not know what is going to be valuable until they look back.
- Dixie Baker emphasized that they want to be measuring outcomes across a continuum of care and not just in one specific place among that continuum.
- Dixie Baker also noted that the Privacy and Security Tiger Team recently made a recommendation that the notice of privacy practices be presented in a layered approach in which the top layer is for those who do not want to see all 10 pages of the notice of privacy practices. They could see a very articulate, short summary. Then, if they really wanted, they could go to lower and lower layers. This makes sense for patient information as well. Through a structured container, information could be presented at the very top, basic level. Or, if a patient wanted to dig down deeper, they would be able to obtain more information in a more structured form.
- John Halamka noted that there may be an ecosystem of vendors that could present patient information in novel ways. Some might be graphical, and some might be in lay language. It is up to the provider organization to provide the data elements.
- Janet Corrigan noted that the fear of attribution issue is a significant challenge. In recent years, it has had a negative impact on measure development. She asked if there was any creative thinking on this issue, perhaps to try to move the reward pools, whether they be HIT incentives or shared savings reward pools under the payment demonstration projects, up to the community level. There is a need to determine how best to make financial rewards available, tie them directly to those measures, and provide some assurances to clinicians that the idea is not to take health functioning down to the individual clinician level. There also must be a messaging and an educational effort that helps assure people that this information is going to be used responsibly when it comes to assigning the financial rewards.
- In response to a comment about timeline issues for 2013, David Blumenthal indicated that the ONC hopes to have a new set of proposed measures, although the timing of this is unclear. It would be helpful to know the amount of time that is required to develop standards for newly proposed measures, how much time the HITSC would need, and how that might affect the calendar. He reminded Committee members that they can propose measures in the Notice of Proposed Rulemaking (NPRM) and then withdraw them if the standards are not ready, as they did in the first round of meaningful use.
- In response to another comment, David Blumenthal explained that a dilemma facing this work is that there is a substantial reluctance in health care communities to vigorously exchange information. The focus should remain on what is good for patients, and if some

tension is created around people's needs to get out of their comfort zone in working together in local communities to make care better for patients, that may be a healthy tension that is inherent in this process. The entire health system cannot be reformed through the meaningful use framework. Coordination with colleagues elsewhere in the federal government will be necessary (e.g., working with those focused on the medical loss ratio requirements so that insurance companies are also incented to participate in promoting exchange of health information, since they are major beneficiaries of exchange).

- Jim Walker commented that at present, the rate-limiting step for his organization is how fast it can connect organizations to HIE. They are moving through it expeditiously, and they can manage most of the people who see the business case now. If everyone saw the business case tomorrow, they could not hire and train enough people to connect them all. The State of Pennsylvania has repeatedly indicated that it will not connect people to the state HIE because they do not have the necessary skill sets. Jim Walker noted that there are Beacon Communities in states that do not have HIE, and part of the Beacon Community process is to stand up an HIE.

6. NHIN Direct: Current State and Lessons Learned

Arien Malec reminded the group about what the NHIN Direct project is, and that its value lies in enabling information liquidity. For example, EHRs are needed that can both generate quality measures and help facilitate decision support, which is incredibly difficult to do if the information is captured on paper rather than electronically. They hope to provide a simple, obvious path for directed exchange. More than 60 organizations and 200 participants are represented in the Direct project.

They are working on specification development activities and real-world implementation activities and recognize that there is a set of policy activities that are taking place in parallel, which at times has been slightly difficult. There is a strong and effective working relationship between the Direct project and the tiger team, in which the tiger team essentially works ahead to provide appropriate policy context and guidance.

When this project winds down, a set of draft specifications, which should be announced in the next month or so, will be presented to the Committee. The intent is to transition the specification work to one or perhaps two standards development organizations.

At the same time, the NHIN Direct project is gearing up towards initial pilot implementations. There is a large set of initial pilot implementations, many of which are expected to undergo testing in November, with spin-up to their first provider connections in December of this year. Although the project started with a focus on transport, in the context of these pilots, it is moving into areas that involve plugging that transport into context, standards, and specifications, and integrating the transport specifications with elegant provider workflow.

Arien Malec presented key positive lessons from the Direct project: (1) focused problem-solving around a particular business case drives engagement, (2) asking participants to commit to implementation and pilots drives positive behavior and focus, (3) the policy tools at ONC's

disposal work to engage industry broadly, and (4) open-source reference implementations are key tools to promote standards adoption by lowering the total industry cost to achieve the value chain. Arien Malec also discussed key improvement lessons. For example, the implementation group grew too large, too fast. It is recommended that the commitment bar in the future be set even higher, with firm limits on the number of participants. Focus is driven by driving to code and driving to implementation—it is recommended that earlier milestones be set to work code and pilot test. Another key improvement lesson is that the U.S. HIT standards world has fundamental philosophical splits (e.g., quality first vs. liquidity first?). Another tension, one related to reaching consensus, relates to trusting the community or establishing an independent trusted review.

Related to the “trust the community” option, Arien Malec presented the project’s pre-July findings:

- There is a need to support structured and unstructured content, often in the same transaction.
- XDR/XDS had implementation support in many modern EHRs.
- XDR needed modifications to separate transport metadata from content metadata.
- XDR and XDM have strong support for comprehensive content packaging with package-level metadata but the broadest range of providers could not be expected to produce such packaging.
- Something more ubiquitous is needed to support the broadest community of providers.
- The trust model required a relatively sophisticated approach to encryption and signatures.

Arien Malec noted that the project has an open-source code repository that has been generating high-quality code at a high rate since July-August of this year, driving in just a few months to a substantial set of reference implementations that can be taken out of the box and used to implement the NHIN Direct specifications. In conclusion, Arien Malec indicated that he stands by the group’s decision to trust the community, while acknowledging that there have been a few common objections. For example, it has been brought to their attention that: (1) the choice of SMTP is a step backwards from structured content, Healthcare Information Technology Standards Panel-endorsed standards; (2) SMTP carries with it spam, identity spoofing, privacy risks, etc.; and (3) certificate distribution is a difficult problem.

Before the presentation continued, there was a brief Committee discussion session, during which the following points were made:

- John Halamka asked for some discussion about REST, which is the one transaction the group is not supporting at all. He noted that SureScripts uses REST, as does Facebook. Doug Fridsma commented that REST was the approach that had the least amount of objection, but it also generated the least amount of energy in the group. The comments in favor of SMTP were twofold. First, reliable store and forward messaging that is nationwide in scope is a

solved problem, and it is all built on top of an SMTP infrastructure. Secondly, SMIME as the content encryption and verification or digital signature approach is nicely embedded into an SMTP workflow and helps drive potentially wider adoption in use than otherwise. They also heard from organizations that are in the business of large-scale transactional support that they can actually make all of these approaches work. The focus instead was on what was needed to engage providers: meet EHR vendors where they are now, which is XDR and build on top of XDS and SMTP.

- In response to a comment by Marc Overhage, Arien Malec said they believe they need to enforce at least an understanding of strong trust models that encompass identity, privacy and security, and transparency. He also noted that there is a significant difference between the latest version of an EHR and what is available now in the community. Almost all of the leading EHR companies have a preference for SOAP-based transactions.
- Jamie Ferguson noted that one of the goals of this project was to have a number of implementations with real-world providers in the September timeframe. Arien Malec indicated that the work took longer than they had expected, and now they are looking at November for testing and December or January for initial pilot implementation. He expressed hope that the HITSC can offer a multi-phased evaluation of the project, with a particular focus on the specifications and reference implementation. David McCallie suggested Committee evaluation after there is an actual implementation. The group arrived at March as an acceptable time for the evaluation.
- Wes Rishel commented that the best outcome would be to demonstrate that this is working well enough to begin certifying for it, which would ease adoption.

Doug Fridsma then continued the presentation with a discussion of the standards and interoperability framework and the notion of focused collaboration. With regard to organizing the standards and interoperability framework, they want to achieve focused collaboration and the creation of processes that are transparent, that people can engage in directly, and that can rapidly iterate and produce results. Ideally, he would like for the focus to be on the type of national goals that are within meaningful use: quality, cost, access, public health. To support those national goals, robust interoperability across settings of care is needed. The next set of projects should support those national goals to create robust interoperability, and then the standards and interoperability framework should be used to support that work.

In moving forward, Doug Fridsma explained that they can select very clear problems to solve. For example, their target might be to reduce the cost of developing a laboratory interface by 90 percent. That means that every piece along the value chain must respond. His fear is that the standards development organization will develop a standard, implement it, and although nothing has been tested and they do not know if it actually solved the use case, they will have met their milestone. A document will have been created, but no one will be sure how to actually implement the standard. Then, software developers will take that information and develop working code—on time and under budget—that will have 50 different configuration switches and a very complicated interface. In this situation, everybody will have done their job across the board in terms of project management, but they will not achieve the national goal of reducing the

cost of a laboratory interface by 90 percent. To avoid this, a structure or process is needed—Doug Fridsma proposed organizing the standards and interoperability framework around setting specific priorities that drive value across the entire value and food chain, using it not as an entity in itself, but as a supporting structure. He presented the following themes:

- An organizing principle is “solving problems” throughout the entire value chain, and using this as the “glue” for the other metrics.
- Each team in the standards and interoperability framework will assist in solving a problem.
- Operationalize the process and problems with metrics, risks, and milestones.
- Solve value-focused problems in small increments; build consistency across projects through a national vision and a model-based approach.
- Balance between bottom-up, goal-directed coordination and top-down, structured coordination.

In discussion, the following points were made:

- Chris Chute asked whether the standards and interoperability framework could be compared to the Internet Engineering Task Force (IETF), the organization responsible for the Internet. One of their principles is to entertain no standards unless working prototypes with at least two adopted representations can be brought forward. Furthermore, they have an emphasis on parsimony; that is, many standards are not good, but a small number of core, well-engineered, fundamental standards seem to work for these ultra large-scale systems. Health care is arguably evolving toward an ultra large-scale system that would be in demand of these parsimonious interoperability standards. Doug Fridsma indicated that he does not think that the standards and interoperability framework is comparable to the IETF, but the principle of adopting no standard unless it has actually been used more than once is an important one.
- Cris Ross asked what this effort will produce. He commented that he did not understand whether the ONC, for example, is going to develop a lab interface. This might be a good idea, but are labs going to be required to use it? What standards process will it go through to determine if it meets meaningful use standards?
- Arien Malec used the ambulatory lab interface as an example. If the goal is to reduce the cost by an order of magnitude, then part of what needs to be done is to assess the current obstacles. What is the current cost chain and value chain for a lab interface? Where are there interoperability issues, and how can those be attacked in a focused way? As they go through this process, the goal of the standards and interoperability framework is to make sure that the endpoint of that particular process is a package of the same standards or specifications that would be useful for solving a lab interface problem in other contexts. The goal of the standards and interoperability framework is to achieve value across multiple iterations and make sure that there is consistency across those iterations.

- Jamie Ferguson suggested that having a fixed timeframe where they start a new project every 2 months may not fit if there are dramatic differences of orders of magnitude in complexity of those projects—and there probably will be. He characterized the issue as one in which very complex projects can be broken down into pieces of roughly equivalent complexity so that they can be regularized in terms of schedule and process.

7. Public Comment

- John Feikema, President of VisionShare and a member of the Best Practices Workgroup within the NHIN Direct project, said that one of the elegant aspects of NHIN Direct project is that it introduced and formalized the notion of a health information service provider as an option, not as a requirement. One of the things they are looking at, for example, is exposing REST services as an edge connector so that those communities that can deploy REST effectively and use it without needing to worry about the backbone protocol. He also noted that that certificate distribution is difficult, but not impossible. They have issued more than 16,000 certificates across the country. The challenge is having uniform policies so that people know what certificates they can trust, who they have been issued by, and under what circumstances.
- Richard Singerman, Chief Innovation Officer and cofounder of TrustNet MD, reminded the Committee of the very pressing timeframe, and urged members not to take on a holiday mentality and put off hearings and other work until January.
- Robin Raiford, Executive Director of Federal Affairs at Allscripts, pointed to the ONC frequently asked questions documents relating to questions 14 and 16, which essentially indicate that those who have done substitutions cannot use vendor certification but must instead self-certify. This will greatly affect many people. Robin Raiford visited an organization last week that is carrying out 1 million computerized physician order entries per month and is now at risk for not being able to participate in 2011 meaningful use because it did not realize that it had to have medication reconciliation in place. The organization believed it could defer this until Stage 2. She suggested that the Meaningful Use Workgroup membership should include a nurse who could inform discussions on medication administration and nursing care plans.
- Keith Boone, a standards architect with GE Healthcare, shared his concerns about how the standards and interoperability framework plays out. He emphasized the need to ensure that those activities that are prioritized the highest are really of value. He also pointed to the need to recognize that not all of these activities will come together and work on the same schedule.

SUMMARY OF ACTION ITEMS

Action Item #1: Minutes from the last HITSC meeting, held on August 30, 2010, were approved by consensus.