

# Health Information Technology Standards Committee Final Summary of the May 18, 2011, Meeting

## KEY TOPICS

### 1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 25<sup>th</sup> meeting of the HIT Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available on the ONC Web site. She conducted roll call, and turned the meeting over to National Coordinator for Health Information Technology Farzad Mostashari.

### 2. Opening Remarks

Mostashari thanked the Committee for its work, noting that one of its most important activities remains advising on standards for meaningful use. He added that this meeting would include a presentation on meaningful use Stage 2, which reflects some guidance offered by the HIT Policy Committee (HITPC). The meeting's overall focus would be on interoperability framed in several different ways, such as transactions, queries, and quality measurements. The public has expectations that these issues will be dealt with. In moving towards 2015 and beyond, interoperability will need to extend to all the other industry aspects as well, including better payment systems, better care, and quality measurements that are done to, by, and for the electronic health care system.

Mostashari welcomed and introduced the Committee's newest member, Rebecca Kush, President and CEO of the Clinical Data Interchange Standards Consortium, a non-profit organization that develops data standards to allow interoperability to improve medical research.

### 3. Review of the Agenda

HITSC Chair Jonathan Perlin welcomed and thanked the group for its efforts. The Committee approved the minutes from the April 20, 2011, meeting.

HITSC Co-Chair John Halamka reviewed the tasks that must be completed between April and September in order to get regulations written in time for the meaningful use Stage 2 deadlines, and applied that list to this meeting's agenda. In April, recommendations on certificate management were completed. The Metadata Analysis Team was formed to examine universal exchange, so that as they look at lessons learned from the President's Council of Advisors on Science and Technology (PCAST) Report, recommendations to move forward can be developed. The Committee also created a group to address patient matching.

For May, e-prescribing of discharge medications from the hospital will be considered by another new group. Preliminary vocabulary recommendations are going to be considered, as are recommendations around individual-level provider directories (ILPDs). In June, a team will be

considering surveillance implementation guides, and will be creating a concrete implementation guide. Another group will consider quality measures. ONC will be putting leadership into place for a group to examine electronic health record (EHR)/personal health record (PHR) data exchanges. In July, the Committee will be taking on a review of Standards and Interoperability (S&I) Framework activity, to include lab simplification, transition of care, and cleanup of standards. They will also hear about and work on the Nationwide Health Information Network (NWHIN), and in August, they will discuss distributed query standards.

Mostashari acknowledged Doug Fridsma for his H-L7 work related to challenging S&I Framework issues. One of the core principles is to make sure the benefits of HIT can reach everyone. As they navigate between keeping an “eye on the prize” and “feet on the ground,” it is important to design this in a way that is accessible and as simple as possible.

**Action Item #1:** The Committee approved by consensus the minutes from the April 20<sup>th</sup> meeting.

#### **4. Meaningful Use Stage 2 Update and Discussion**

Meaningful Use Workgroup Chair Paul Tang updated the group on the latest activities of the Health Information Technology Policy Committee (HITPC), which will be delivering final recommendations at the June HITPC meeting. He shared the group’s work plan, which began last year with Stage 2 hearings and will end with the HITPC June 8 meeting. Tang stressed that this is a work in progress and the Workgroup would like to entertain the Standards Committee’s general questions about its philosophy and approach.

Tang and Workgroup Co-Chair George Hripcsak then presented a series of slides showing meaningful use Stage 1 final rules and proposed Stage 2 rules. Items that are new compared to Stage 1 were presented in blue; red text showed edits that were made as a result of public comment and comments from HITPC.

Next, Tang discussed the issue of timing from meaningful use Stage 1 to Stage 2, which has been a concern. He noted that overall, the program is aggressive. There is a conundrum for the early group of adopters that enter Stage 1 in 2011. The hospitals in this group could need to start their reporting period as early as October of 2012 for the 2013 reporting year, leaving almost no time for vendors to develop Stage 2 products or for providers to implement them. That is an unworkable challenge, but it only applies to that one small group. To address this issue, Tang presented three possible timing solutions, and then walked the Committee through a table that highlighted the pros and cons of these three timing schemes. He said that the Workgroup is open to other suggestions as well.

#### ***Discussion***

- John Halamka highlighted some standards gaps and suggestions. With regard to expanded demographics code sets, the IOM 2009 report suggests granular categories in HL-7 code sets. He asked whether this might be a Vocabulary Task Force assignment. Regarding smoking status and its expansion to now include secondhand smoke, he asked if that is another code

set issue to be assigned. Also, LOINC is specified for structured labs, but SNOMED is also an appropriate code set for organisms and microbiology.

- Regarding the electronic medication administration record (EMAR), Halamka indicated that he is not certain this has been adequately defined for these efforts. Different standards can be implied depending on the workflow—which depends on the definition. Also, that the long-term care plan is noted as something that will be merged into the summary care plan, but he questioned whether there is any standard for this other than free text. With regard to reportable cancer conditions, he pointed to the *IHE Cancer Reporting Standards Guide*, and asked if there are others.
- Halamka also pointed to a recent Office of the Inspector General (OIG) report criticizing some of the work this group has done. He suggested that perhaps they did not go far enough beyond technology in their recommendations to address business processes.
- In reference to the objective that 20% of hospitals' discharge medications lists be sent electronically, Jim Walker said that his organization was ready to do so 6 months ago but decided not to, because most pharmacies are not able to receive cancellations of medications. His group felt it was unsafe to begin sending electronic discharge medication orders until pharmacies are able to receive cancellations.
- Walker also said that they had a successful experiment with putting electronic formulary information in their order information system, but they were unable to continue it because they could not afford the cost of hand-entering just one formulary. A rational approach would be to indicate that formulary owners are required to provide formularies in a standard electronic format before providers are required to use them. Walker also noted that small practices and hospitals have little leverage with some lab systems. If hospital labs are required to use LOINC and commercial labs are not, it could put hospital labs in a more competitive position. He also noted the need to ensure that any elements that are standardized have a clinical applicability.
- Chris Chute commented that the standards appear to be fairly low for exchanging data with colleagues compared with the requirements for providing patients with data. There is a connection between these activities, and he questioned raising the bar on patient communication but not on colleague-to-colleague communication. Perlin agreed, adding that beyond consideration of Stage 2, there is also a discussion about Direct and the NWHIN, what interchanges might occur using what supports, and by whom.
- Walter Suarez recommended that the Committee the option to delay the transition from Stage 1 to Stage 2 by 1 year. There are some questions out there about whether this is consistent with the Health Information Technology for Economic and Clinical Health Act (HITECH), but nothing in the law prohibits a change in staging. ONC's Josh Seidman clarified that the law prohibits a skipped year on the Medicare side, hence the third timing proposal. Seidman pointed out that this does call into question the issue of menu versus core items and the introduction of new objectives.

- Wes Rishel suggested that there be a meaningful use requirement on health care providers to use formularies only in cases where a payer has voluntarily certified their way of electronically transmitting formulary information. In that way, there is no obligation on payers to certify, but there is a big possibility of return on investment in terms of subscriptions.
- Regarding timing, Elizabeth Holland said that they had originally proposed what the stages would be for 2015, but this information was not included in the final rule. The difficulty is that 2015 is the year that the penalties begin. It is anticipated that the Notice of Proposed Rulemaking (NPRM) will include information about how the penalties would be levied and at what level. It was noted that 2016 is the last year for incentive payments for Medicare. Wes Rishel said that before they get to the NPRM for Stage 2, they need to extrapolate the timing table out to Stage 3 and have a fair idea of whether things are connecting appropriately.
- Marc Overhage pointed out that there are workable formulary standards that currently exist. However, formularies as they are currently constituted are large, unwieldy, and expensive to maintain and integrate meaningfully into the system. This is a business process issue as it stands, but he suggested that it be addressed as a standards issue—the existing standard is usable, but at a significant cost. An evolution of that standard may be in order.
- Jamie Ferguson discussed the increase in problem list requirements for Stage 2. In looking at available vocabulary subsets for problem lists that could be used in certification, there are two flavors. One is the most recent release from the National Library of Medicine (NLM) and represents the top 2,500 SNOMED problems, which is exclusively findings and disorders. The other available subsets are generally larger. One download is about 6,000 items, mostly procedures, therapies, medications, and things other than problems. What should be in the problem list? Actual problems, or a catch-all list? Tang concurred on the need to define the problem list. HITSC input on this issue would be helpful.
- Jim Walker commented that items on a problem list are things that might require intervention, such as monitoring, treatment, discussion, etc. He compared problem lists to allergy lists, in that items that are included on allergy lists are often just drug contraindications, not true allergies. David McCallie suggested that the fact that the problem list has not been well maintained indicates that the appropriate utility for it has not been discerned. There is a need to determine how to make the problem list more useful and therefore more valuable to keep up to date.
- Guidance on the balance between the work of standards versus implementation challenges is needed as work progresses into Stage 2. Kevin Hutchinson pointed to Jim Walker's example of the challenges pharmacies have had on cancelled or changed orders. That is an implementation issue—how much of that does this group address with respect to workflow versus establishing a standard? Hutchinson also pointed to the need to revisit how auditing and ensuring compliance will be addressed. In addition, he asked whether there is a particular goal that is being established at the HITPC level as to quality improvements. It

was noted that the Meaningful Use Workgroup will be hearing a Centers for Medicare and Medicare Services (CMS) presentation on these issues.

- John Derr noted that the discharge medication lists are only for patients, and are assuming that patients are going home. However, many people go to skilled nursing facilities. Hospitals will want to know whether they include these cases in their discharge counts. He offered to share this information with some of these long-term care facilities and add comments. Such facilities are not included in the legislation, but they are working to ensure interoperability because that is what is best for patients.
- Carol Diamond spoke about the issue of privacy and security that were highlighted in the OIG report. When it made recommendations for Stage 1, the HITPC had not yet formed its Privacy and Security Tiger Team. She suggested that the HITPC flags this issue in its meaningful use work: there will be new security requirements from a technical standpoint, but the policy processes from the Tiger Team will affect them.
- Dixie Baker commented that HITECH indicates that if the patient requests that an electronic copy of their record be provided to a third party, such as a PHR, that the provider must comply. She suggested specifying that it is the capability to provide an electronic copy to a third party in a standardized format. This is consistent with the recommendations from the PCAST Report Workgroup.
- One Committee member reminded the group that it cannot forget about privacy and security with respect to downloading. Downloading in clear text is not appropriate.
- David McCallie suggested that the Direct protocol could fulfill a number of the use cases associated with this work. Sending a copy of electronic information, regardless of the format, to another provider or to the patient using Direct is feasible and within scope for the protocols. He suggested the group consider the ability to interact through Direct as a requirement for Stage 2. Also, he suggested that as they start envisioning multiple ways that a packet of information could move from sender to receiver, they should make sure their focus on the provenance of this information includes a digital signature. This is not the same as encryption, but it could go along with encryption. It makes the data tamper-proof, and will increase the value of these intermediate mechanisms.
- Janet Corrigan commented that a good care plan has goals, and suggested that the Committee begin to move towards measures that include a dashboard to view patient goals (e.g., weight loss). Without this capability, there likely will be many frustrated practitioners who will have to put long-term health care plans in place with or without standards. Nancy Orvis pointed out that if the Committee is going to propose criteria for care plans, then a reference definition of a care plan is needed. She also suggested a clarification of whether a care plan contains expected “due by” dates. An active care plan has expected dates for both practitioners and patients.

## 5. Privacy and Security Standards Update

Privacy and Security Standards Workgroup Chair Dixie Baker presented recommendations for EHR queries of enterprise-level provider directories (ELPDs). She started by discussing the needs as identified by the Policy Committee, and shared the results of public testimony received so far by the Workgroup. She then presented the recommended standards, implementation specifications, and certification criteria.

### *Discussion*

- Dixie Baker explained that there are multiple ways of retrieving a digital certificate for a selected entity: LDAP, PKI, etc. The certification criteria address what an EHR must be capable of doing. These standards address how to retrieve a digital certificate from an entity-level provider directory (ELPD).
- David McCallie clarified that there is no intention that Direct could wait with widespread deployment of LDAP. DNS can be used right away.
- Doug Fridsma asked if there is the capability to retrieve a digital certificate and whether this capability would close out some of the implementation of Direct that exists today at present. Or, would the Workgroup like to see the use of Direct as a Stage 2 criterion? McCallie clarified that the discovery of the certificate is not part of the Direct protocol. The decision for how to distribute certificates is important, so the DNS solution to certificate discovery is a secure, workable, highly scalable approach. Given Stage 2 timing, he is not sure he would consider the ELPD part of it as a short-term test. The critical component is ensuring that the protocol side is handled correctly and capable of the S/MIME requirements.
- Marc Overhage noted that one of the group's core principles is that these things should be live and in use somewhere, and questioned the current trajectory. He indicated that he has not seen any indication that REST is included in the IHE protocol. Baker agreed that it is not included yet, but testimony from previous hearings has indicated that it supports both REST and SOAP. Overhage commented that he would like to see this documented.
- One Committee member acknowledged that the Workgroup's recommendations represent the current state of the art and noted that if they are included in certification criteria, they are in effect asking the industry to move on these in the next 18 months.
- Another Committee member suggested that if the Workgroup believes it is important that there be a certification criteria that a certain function exists, the Workgroup can simply indicate that the functionality needs to exist—they do not need to specify LDAP, for example.
- Cris Ross discussed a number of issues. For example, the work still has not been done to match up meaningful use requirements against protocol standards. The Workgroup has divorced transport from content and container. He noted that it is difficult to identify an

industry that has an exhaustive industry-wide directory. Other highly automated industries have managed to avoid having such a directory.

- Carol Diamond suggested that the Committee cannot make a decision about standards until the issues that Cris Ross outlined are further developed. There should be a dialog to refine the requirements that are necessary as well as a refinement of the request along with some technical advice.
- The Committee tabled the discussion on the Privacy and Security Standards Workgroup, with the recommendation that the HITSC work with the ONC and HITPC to refine requirements for ELPDs.

**Action Item #2:** The Committee tabled the recommendations of the Privacy and Security Standards Workgroup, with the recommendation that the HITSC work with the ONC and HITPC to refine requirements for ELPDs.

## **6. Clinical Quality Workgroup Update**

Clinical Quality Workgroup Chair Jim Walker noted that a hearing was scheduled for the day after this HITSC meeting that would include a spectrum of implementers, manufacturers, and others to discuss early experiences with meaningful use Stage 1. Beyond that, the Workgroup is creating power teams to work with Floyd Eisenberg on some specific measures and to address vocabulary and other standards needs. He anticipates having some concrete findings to report at the next meeting.

### *Discussion*

- Judy Murphy noted that the Committee has spent a great deal of time looking at meaningful use Stage 2 issues, but it has not vetted or discussed quality measures as they relate to standards. In Stage 1, these were difficult issues, so the sooner the Workgroup and HITSC can move in this direction, the better. It was noted that quality measures will be proposed in the NPRM, and will be needed in August.
- Kevin Hutchinson asked, if the focus will be on clinical quality measures in meaningful use Stage 2, what is the goal that they are trying to measure? He questioned the purpose of reporting of conditions without knowing whether they are having any impact. Impacts through isolated examples are known, so perhaps the Workgroup could focus around two or three major clinical items to be achieved by 2015. That would provide some basis on which to establish the standards work that needs to be done to achieve those goals. He recognized that this is probably outside the purview of this group, but if it would be helpful if they could help promote this concept.

## **7. Implementation Workgroup Update**

Implementation Workgroup Co-Chair Liz Johnson presented the Implementation Workgroup's upcoming workplan and timeline. Co-Chair Judy Murphy directed the Committee to a 17-question survey the Workgroup has developed to obtain meaningful use Stage 1 implementation feedback. Respondents can post comments online, or they can download the document, complete it, and submit it via e-mail. The Workgroup will summarize the results by constituency and will present the findings at the August HITSC meeting.

## **8. Clinical Operations and Vocabulary Task Force Update**

Clinical Operations Workgroup Chair Jamie Ferguson explained that the Vocabulary Task Force's first order of business is to assess the previous vocabulary definitions of this Committee, given that there have been a number of transmittal letters, including vocabulary recommendations. The Task Force will assess whether those recommendations are still valid, and examine the readiness of vocabulary and supporting technology for the industry.

He posed the following general question: is it possible to have a certification requirement precede a meaningful use requirement? In terms of implementing standardized vocabularies for medications, if the electronic medical record (EMR) is capable of it and if the vendor has supplied that sort of support, then the subscriber could go through a multi-year process of testing, implementing, etc. That can only happen after it has been deemed a part of meaningful use.

Regarding medications for e-prescribing, Ferguson explained that four components of RxNorm should be required (semantic clinical drug, semantic branded drug, generic package, branded package), and that the Task Force is still developing recommendations on timing and readiness for RxNorm.

In terms of medication allergies, the Task Force is recommending RxNorm and UNII for inactive ingredients and non-drug allergies.

With regard to lab results and orders, Ferguson explained that the Task Force is working on medications first, then labs, then problems. Lab recommendations are up next for the Task Force, and it has already had some discussions on this topic. There is not an acknowledged or widely used standardization of lab order messaging. Identifying vocabularies for lab orders must be done in conjunction with the standardization of messaging.

### ***Discussion***

- Chris Chute noted that the LOINC/SNOMED question has a decade or more of inertia behind it. There is an expression: if SNOMED is the answer, then LOINC must be the question. That is, SNOMED is used for results; LOINC is used for orders. It is important not to confuse the notion of results with the notion of orders.
- Halamka indicated that he did not believe that standardization of lab orders is an objective for meaningful use Stage 2. Ferguson agreed, noting that if it is going to be included in Stage 3, this work has to be done now.

The Workgroup is going to develop problem list recommendations after it develops the lab recommendations. A reference was made to the discussion earlier in the meeting about whether the problem list is a catch-all, or more tightly defined as problems and findings. From a vocabulary subset perspective, for certification purposes the Task Force may limit itself to a subset of disorders and related items.

### *Discussion*

- David McCallie indicated that he is somewhat confused by the notion of subsets and what it means for legitimate codes that are not in the subset. Would those be only the codes that the EHR would be required to support? Would other subsets be in the pick list?
- Halamka suggested that there could be a Web site where a set of vocabularies and subsets existed that represent the most common problem list. Then, should a new list item come along, a practitioner would be able to incorporate it. McCallie said that even a 6,000-item core subset does not contain some fairly common diseases.
- Wes Rishel explained that if only the problem list subset is required for certification, it must be made clear that the subset includes all of the problems necessary to generate all the data for the quality measures. Ferguson confirmed that this will be the case. There will be a cross-check, or a dependency between the value sets and the performance measures. Rishel continued by stating the need to certify the handling of a new, incoming code that is not already in an EHR's code tables. If this step is not taken, it will introduce a number of significant interoperability issues.
- Jim Walker asked if a system receives a SNOMED code, whether it is part of the certification that it can consume it and implement it as a SNOMED code. Halamka indicated that this is not clear. The Task Force is only dealing with requirements for transferring data "over the wire." Rishel explained that currently, when an EHR is certified as a user of an e-prescribing product, the certification includes the notion that it can actually do something with the data it receives. The format does not matter, but if for example this is the floor for the number of SNOMED codes for a problem, and those codes drive data aggregation for quality or decision support, then there ought to be some mechanism so that it can receive information and deal with it semantically.
- Halamka explained that this body of work is more about accelerating EHRs to have starter sets. Ferguson acknowledged that the points Walker and Rishel raised make sense, but they are outside the scope of the Vocabulary Task Force's scope. If the Committee agrees, they could create those functional criteria. Rishel suggested that they learn whether the National Institute of Standards and Technology (NIST) has been charged with doing this, because it will affect the work of this Committee.
- Doug Fridsma pointed to the need to provide the industry with a directional statement, to help move incrementally towards semantic interoperability. He agreed that having the ability to query a series of vocabulary services is something that should be enabled, but in getting to that point, there also must be the ability to indicate, for example, that there was a recent

outbreak of H1N1 and this is not in everyone's vocabularies yet. A new code such as this cannot break the system. It becomes critical to work with NIST so that systems conform to a set of subsets and are able to send conservatively to conform to a standard, but also to have a mechanism to query a service to look up codes that are not on the list, or else to have a human readable definition of the code available for those outside of the basic codes.

- Rishel suggested that the sender send a human-readable expression of the code along with the code itself to help deal with a system that is already in use for codes outside the base set.

## **9. Update on “Summer Camp”**

ONC's Doug Fridsma stepped through some of the activities planned for the summer. Several power teams are being formed to analyze various specific issues, as follows: (1) Metadata Analysis, chaired by Stan Huff; (2) Patient Match, chaired by Marc Overhage; and (3) E-prescribing, chaired by Jamie Ferguson.

Stan Huff offered a brief presentation on the Metadata team's work on patient identity, highlighting the suggested metadata and standards.

### ***Discussion***

- Regarding the granularity of a physician's ID, Huff pointed out the importance of messages being traceable back to the responsible party.
- McCallie said that a patient might want to change what they consider to be sensitive information at some point in the future. This could be a fairly normalized model. If the sensitivity declaration is pushed down to the time of care, though he is not sure if that will work in all cases.
- Kevin Hutchinson said that based on the experience they had in trying to help out with medical histories after Hurricane Katrina, the privacy standards are going to need to be flexible to adjust on a state-by-state basis, to reflect differing state laws.
- Jodi Daniel indicated that from a federal perspective, all health information is sensitive. State laws are different, which presents certain challenges. She suggested the notion of having a patient's preference for sensitivity be a flagged item, so that patient sensitivity can be reflected as an on/off just as state and federal law can be on/off.
- Dixie Baker pointed out that if a patient changes his or her mind about what kind of data can be shared, it must be understood that this will create complications.

## **8. Public Comment**

There were no public comments.

## **SUMMARY OF ACTION ITEMS:**

**Action Item #1:** The Committee approved by consensus the minutes from the April 20<sup>th</sup> meeting.

**Action Item #2:** The Committee tabled the recommendations of the Privacy and Security Standards Workgroup, with the recommendation that the HITSC work with the ONC and HITPC to refine requirements for ELPDs.