



HIT Standards Committee FINAL Summary of the May 21, 2014 Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 57th meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with an opportunity for public comment (three-minute limit), and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Review of Agenda

Chairperson Jacob Reider, ONC, asked for corrections of, additions to, or approval of the summary of the April meeting as circulated. It was moved and seconded to approve the minutes and the motion carried unanimously by voice vote.

Action item #1: The summary of the April 2014 HITSC meeting was approved.

Reider announced that in addition to the two important items on the previously distributed agenda, several members had requested the addition of another item—the May 20 announcement of a NPRM by CMS to help providers make use of Certified EHR Technology (CEHRT).

CMS NPRM to Help Providers make use of CEHRT

Elise Anthony, ONC, gave an overview. She emphasized that she wished to summarize and clarify the announcement. She was prohibited from offering an interpretation. The announcement is consistent with a previously announced intent. The rule would provide an additional year for providers to stay at Stage 2. EHRs would have until October 2016 to move to Stage 3, and EPs would have until January 2017. The proposed rule would let providers use the 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT for the EHR reporting period in 2014. Beginning in 2015, all eligible hospitals and professionals would still be required to report using 2014 Edition CEHRT. Providers that are not able to fully implement the 2014 certified technology would be able to use 2011 certified technology or a combination. She referred them to the table in the rule that showed the proposed changes in the timeline and the available options.

In response to a question from Wes Rishel, she said that there is a 60-day comment period. Although a specific date cannot be given, CMS officials have indicated that the final rule will be published before the end of 2014. She clarified that EHRs may use 2011-certified products through FY 2014 and for EPs, the calendar year 2014 is the permitted period. If a provider is scheduled to move to Stage 2 in 2014, the provider would be able to attest to the 2013 Stage 1 objectives and measures. If a provider is scheduled to move to Stage 2 in 2014 and is using the 2014 CHERT, there are two options. Anthony again referred members to the table for specifics.

JASON Report

P. Jonathan White, AHRQ, showed slides and described major findings from the report commissioned by AHRQ and RWJ, acknowledging that they are not surprising. The current lack of interoperability among data sources for EHRs is a major impediment to the unencumbered exchange of health information and the development of a robust health data infrastructure. Interoperability issues can be resolved only by establishing comprehensive, transparent, and overarching software architecture for health information. The twin goals of improved health care and lowered health care costs will be realized only if health-related data can be used for both clinical practice and biomedical research. That will require implementing technical solutions that both protect patient privacy and enable data integration across patients. He pointed out that for the purposes of this report, software architecture defines a set of interfaces and interactions among the major components of a software system that ensures specified functionality. JASON delineated the following principles:

- The patient owns his or her data
- Be agnostic as to the type, scale, platform, and storage location of the data
- Use published APIs and open standards, interfaces and protocols
- Encrypt data at rest and in transit
- Separate key management from data management
- Include metadata, context, and provenance of the data
- Represent the data as atomic data with associated metadata
- Follow the robustness principle: *“Be liberal in what you accept, and conservative in what you send.”*
- Provide a migration path from legacy EHR systems.

A patient privacy bundle is a collection of fine-grained settings of default permission and inheritance settings for access privileges to electronic health data. Both atomic data and metadata must be associated with permissions. The patient controls access by electing a privacy bundle. A fine-grained permission system is flexible, and can accommodate many different types of security policies. The choice of a patient privacy bundle implies an assumption of different levels of risk by the patient in return for different benefits for themselves and society.

The report include a number of recommendations, two of which White presented for discussion.

- Within 12 months, ONC should define an overarching software architecture for the health data infrastructure.
- EHR vendors should be required to develop and publish APIs that support the architecture of the health data infrastructure.

He gave them three suggested topics for discussion: ONC should define an architecture this year; patient privacy and related risk management should be addressed by the use of patient privacy bundles; and the architecture should be supported by openly developed, published, and tested APIs.

Discussion

Arien Malec declared that he supported the direction of the report, which is consistent with ongoing work and PCAST. He asked about any recommendations for the roll-out of the reconfiguration of EHRs. White emphasized that the report does not represent his or AHRQ’s recommendations. The architecture is not just reconfiguration. The report recognizes that data come from many different places; data may even be genomic or environmental exposure. There is no time table. AHRQ officials typically think longer term. First, there will be a discussion of achievability and whether it is a good idea.

Rishel made a statement. Although many agreed on the principle that the patient owns her data, it means different things to different people. The patient can deny access to her data to the people who collected it. But co-ownership must be recognized. He admitted that he had not read the complete

report. The architecture seems to be primarily associated with acquiring data across sources rather than exchange of data for transactional purposes. Atomic data can never present a complete picture of a patient. The picture varies by organization. There are currently no standards on how to structure these data. He opined that reengineering of the most widely used EHRs for atomic data would be a large scale endeavor similar to the meaningful use incentive program. Laissez faire may be the better approach. Ultra-large systems are systems that cannot be managed top down. Any change of that magnitude should be discussed with persons who study these systems. White referred him to page 35, on atomic data.

Eric Rose expressed great concern that the report is an anonymous report. Who is JASON? The persons who authored the report are not named, and information about the company is not publically available. This is not is keeping with HITECH transparency. Advice should be sought from persons with known expertise not anonymous organizations. White acknowledged that the report is not of the usual type. He referred to an article in *Nature* on JASON. JASON is reportedly involved in defense intelligence work. AHRQ is bringing the report to the HITSC for advice.

Stan Huff talked about the time frame of 12 months being completely unreasonable. It implies things that are not yet standardized. Information models bound to terminology are required and they do not yet exist, let alone having been tested to scale. Unproven standards cannot be mandated. The proposal would take two-to-five years. He acknowledged that he liked the other recommendations. White replied that the issue is the definition of architecture and the direction.

Dixie Baker indicated that she agreed with focusing on interfacing and sharing data. She admitted that she had not read the report. She wondered whether the privacy bundles are constructed before sending the data. She said that she agreed with Rishel that the architectural approach was suited more for treatment than research purposes. Perhaps PCAST can be incorporated. White responded that the privacy permissions are associated with atomic and metadata. There would be challenges. Bundle management shown in the diagram is above the stack, not below the encrypted data. He acknowledged that he was unsure about the suitability for research purposes. The full report (p. 47) definitely calls out research. Regarding privacy protected APIs, he referred to his presentation diagram and said that the topic was worthy of further definition.

Leslie Kelly Hall talked about her concerns around the wording and description of the ownership of data being with patients. The property rights are inherent to the person who creates and records the data. The patient has the right to view the data and to download and transmit. These recommendations pivot on the patients' ownership of the data. The restriction of the use of data can cause harm. There could be significant safety issues resulting from these restrictions. If they can be overridden for care, then there is a considerable amount of work to be done without material gain. Why go into that level of detail of internal structure of the EHR? In the report there was nothing regarding PGHD or anything around the architecture for inclusion of the patient in a more collaborative care model. White acknowledged that everyone struggles with the ownership issue. This is not a comprehensive analysis of all laws and regulations applicable to ownership. Patients do have rights to their data. The concept that the organization that collects and maintains the data has ownership rights could be incorporated into the architecture. Currently, data are provider centric. PGHD can be included.

Keith Figlioli said that the key issue for his employer (Premier, Inc.) is first, cost, and second, speed. The way to innovation is slow and costly. Technology will evolve. The recommendations seem logical. Premier's recommendation is to convene a workgroup dedicated to this evolution, to think about APIs, and to take a horizontal approach on how to incrementally get there. White said that the report talks about entrepreneurial space.

Kim Nolan referred to permission levels and talked about data integrity and the uses of data. Many businesses are acquiring EHR data, normalizing, and then selling data sets. There are many integrity

concerns about these data and how they are used and misused. They should not be considered comparable to data collected for research purposes.

Rishel referred to the FACA looking beyond Stage 3 and said that the longer view should not be tied to a specific architecture. Reider announced that ONC was convening a JASON Task Force to review and make recommendations concerning the report. He reminded them that the HITSC's scope went beyond meaningful use. He asked that interested members volunteer for the task force by e-mail to Consolazio.

Malec suggested that instead of another task force, the report review be assigned to the proposed Architecture, Services and APIs Workgroup. Consolazio said that a small task force was preferable. The task force members could then be folded into the workgroup. Reider agreed. (Later that day an e-mail was sent inviting volunteers from the HITSC and HITPC.)

Draft HITSC Workgroup Evolution

Reider showed slides and described the proposed new structure of the workgroups, which was discussed and input received at previous meetings. He said that the workgroup structure will be used to finalize staffing patterns. The Steering Committee is charged to: coordinate and review HITPC policy recommendations to charge the workgroups; define the standards problems and options posed by the HITPC; assure that all stakeholder interests are integrated across all workgroups; assure overall coordination across the workgroups; and report back to appropriate HITPC workgroups for continuity. The Semantic Standards Workgroup is charged to: assure a consistent approach to semantics standards for CEHRT; identify existing standards (vocabularies and/or information models) that can be leveraged for other uses, while ensuring consistent semantic standards across all use cases; identify semantic standards requirements for CEHRT; evaluate new standards or approaches (vocabularies and information models) for representing semantics; recommend a strategy for maintaining a consistent and sustainable approach to semantic standards; and assure consistent linking of semantic standards and content standards. The Content Standards Workgroup is charged to: evaluate current content standards and propose incremental improvements that achieve greater interoperability; recommend an appropriate balance between optionality and constraints in content standards; and provide recommendation on key standards initiatives. The Content Standards Workgroup is also expected to evaluate systems and standards that are resilient to big data approaches and develop a strategy that can accommodate the movement from document-centric standards to data-centric standards. The Transport and Security Workgroup is charged to support standards for security and transport in certification criteria and alignment with the National Strategy for Trusted Identities in Cyberspace (NSTIC). The Architecture, Services and APIs Workgroup is charged to: promote the migration to platform independence application programming interfaces (APIs) that allow third-party programmers to bridge from existing systems to a future software ecosystem that will be built on top of the stored data; determine API architectural framework; develop an incremental API strategy for open APIs to standardized APIs; support migration from interoperability based on what to build (specifications) to interoperability based on how to use (APIs); and determine use cases for the API portfolio. Finally, the Implementation, Certification and Testing Workgroup is charged to: review implementation challenges with existing standards and provide recommendations for how to improve existing standards and testing; recommend testing methods that support the goals of interoperability and information exchange; establish recommendations for how to test workflow and usability; and evaluate sustainable and inclusive approaches to certification and test method development.

Discussion

Vice Chairperson John Halamka assured the members that he had worked with staff to design the structure and to take into account members' feedback. He fully supported Reider's proposed structure, which will leverage the expertise of the members.

Rose said that the proposed structure made sense. He asked for clarification of the distinction between semantics standards and content standards. Doug Fridsma, ONC, responded that underlying HL7 document standards, such as the CCDA, are the reference information model. The information model describes the structure of semantics. There is overlap between the representation of the semantics and the way that those things are substantiated and the structures used to exchange the information. Consistency in the semantics requires understanding how the different bits and kinds of concepts relate to one another. Information models fall between semantics and the content. It would be better to think about how to make sure there is a relationship with vocabularies, value sets and information models in the structures. He agreed with Rose that continued decoupling of information models from document standards is anticipated. One of the challenges is that when information models become too tightly wedded to the structures used to transport them, additional challenges are created. The respective workgroups are encouraged to interact. Rose suggested putting the distinction between content and semantics standards in the charges of the workgroups.

Andy Wiesenthal declared his support for the structure and urged other members to vote in favor of it. He suggested that the structure be assessed at six- or 12-month intervals for fine tuning, rather than trying to fine tune it without experience.

Rishel commented on semantic standards versus content standards. One approach to modeling is top-down to create a canonical presentation of the standards. The approach has not worked. The other model is to go bottom up to enumerate some number of thousands of models and individual clinic data elements and use the higher level standards to talk about ways to combine them into meaningful larger structures. That is the approach ONC has taken. Regarding the interface between the Semantic Standards Workgroup and the Content Standards Workgroup, the Content Standards Workgroup will be under pressure to get things done that rely on on-going work may be out of synchronization with the Semantic Standards Workgroup. Managing that relationship will create the best possible outcome for getting the most semantic specificity into standards. He continued to comment. Somewhere between these two workgroups, the HITSC will have to deal with an issue that will surface in Stage 2—how to deal with negation and relative levels of certainty. To date, the HITSC has dealt with problems by punting, saying that the physician will decide what to do. Reider observed that the workgroups' tasks were being generated.

Jamie Ferguson recalled that at the April meeting there was agreement that usability and workflow are included in the responsibility of the Implementation, Certification and Testing Workgroup. Reider pointed out that usability and workflow were bulleted on the slide. Ferguson admitted that he had not looked at the slide. Reider indicated that the item would be made more explicit. Once the members have agreed on the structure, staff and chairpersons will be assigned and a one-page narrative charge for each group will be composed. Then members will be assigned.

Steve Brown said that VA workers are thinking a lot about semantics and the simplification, and scalability and reproducibility of information models. Semantic operability has yet to be achieved. Knowing what is being done within a single system across various domains and subsystems is a primary challenge. Congress in the current DOD and VA funding bill has called out data reference terminology models. He stated his approval of the proposed workgroup structure and indicated his interest in participating. Reider asked Brown where CDS should be managed. Some components may be content and others semantic; yet, there may be a risk in such a division. Brown responded that the current opinion is that CDS should be built from a smaller building block of terminology and observable units, building on the work of Keith Campbell and starting at the bottom. Separation is a risk that always requires coordination. The division of labor must be carefully managed.

Floyd Eisenberg said that interoperability within a system has not been addressed. The better the data are represented, the better the usability and the CDS management. He emphasized that the Steering Committee will have to be very strong to assure correct alignments.

Leslie Kelly Hall referred to CDS and collaborative care, saying that she sought assurances from Reider that the Steering Committee could make recommendations to inform policy. With collaboration, there are multiple relationships with data. This requires some sort of visionary statement or design principles. Reider said that the HITSC has some responsibility for making the HITPC aware of what is available, although technology must not drive policy. Halamka said that standards empower new and novel workflows. Kelly Hall wondered about members of the workgroups: Will self-nominations from non-committee members be encouraged? Consolazio announced that an invitation will soon be extended.

Dixie Baker said that providers must be assured that by purchasing certified technology, modules can be integrated so that they interoperate, exchange data easily and can be supported by the same CDS support engine. She wondered whether the Architecture, Services and APIs Workgroup has some responsibility for that matter. Fridsma replied, referring to interoperability versus operability, saying that being explicit about the information is a requirement. The same applies to modules. The goal is building blocks of modules that can communicate. Although it is difficult to predict how long that will take, paths can be started. Testing will be daunting. Explicit boundaries are needed. A set of standards and APIs would work like a platform. Halamka interjected that the APIs would be a universal construct.

John Derr asked that ineligibles not be forgotten. Reider reiterated that the committee is not restricted to meaningful use.

Rishel pointed out that in considering operability versus interoperability, the committee should not see itself as regulating the structure or architecture or technology choices made by vendors or other developers. Eisenberg urged caution, saying that in avoiding data model issues, hardwiring of concepts may occur. Reider talked about the distinction between primary and secondary users of information and retaining the intent of the original recorder.

Wiesenthal asked to corral the conversation. The agenda item has to do with the committee structure, not to start the work itself. He moved to approve the recommended structure with the modest modification that it be assessed for fine tuning at six- or 12-month intervals as discussed. The motion was seconded by Rishel. The question was not called. No vote was taken.

Kelly Hall was recognized. She asked that there be recognition that special expertise may need to be brought into workgroups for specific tasks. Reider agreed to add something to that effect to charipersons' responsibilities. Halamka observed that the Steering Committee would be responsible for seeing that each group has the appropriate representation.

Reider noted that with all business complete, the meeting would adjourn 45 minutes early.

Public Comment: None

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the April 2014 HITSC meeting was approved.

Member Attendance								
Name	05/21/14	04/24/14	03/26/14	02/18/14	12/18/13	11/13/13	09/18/13	08/22/13
Andrew Wiesenthal	X	X	X	X	X	X	X	
Anne Castro	X	X	X	X	X		X	X
Anne LeMaistre	X		X			X	X	
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris			X				X	X
Charles H. Romine			X	X				X
Christopher Ross		X		X		X		
David McCallie, Jr.		X	X	X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson	X	X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X	X
Floyd Eisenberg	X	X	X	X	X	X	X	X
Jacob Reider	X							
James Ferguson	X	X	X		X	X	X	X
Jeremy Delinsky		X	X	X		X		
John Halamka	X	X	X	X	X	X	X	X

John F. Derr	X	X	X	X	X	X	X	X
Jonathan B. Perlin	X	X	X	X	X	X	X	X
Keith J. Figlioli	X		X			X	X	
Kim Nolen	X	X		X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher		X	X	X	X	X	X	X
Lorraine Doo		X		X	X	X		X
Nancy J. Orvis			X				X	
Rebecca D. Kush	X	X		X	X	X	X	
Sharon F. Terry	X	X	X	X	X		X	
Stanley M. Huff		X	X	X	X	X	X	X
Steve Brown	X	X	X	X	X	X	X	X
Wes Rishel	X	X	X	X	X	X	X	X
Total Attendees	20	23	24	23	21	23	24	20

Meeting Materials

- Agenda
- Summary of April 2014 meeting
- Meeting presentation slides and reports