HIT Standards Committee
FINAL
Summary of the November 18, 2014 Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 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 (3-minute limit), and that a transcript will be posted on the ONC website. After calling the roll, she instructed members to identify themselves for the transcript before speaking. She announced that Arien Malec, Floyd Eisenberg and Leslie Kelly Hall have been reappointed for 3-year terms.

Opening Remarks

Chairperson Jacob Reider, ONC, talked about what leverage will get everyone to use standards. Standards have been around for years but HIT vendors have not always implemented them. Now there is a new push for value rather than volume. The right standards must be in place, although not necessarily enforced by government. HIT is more than EHRs. EHRs can be dynamic records. The meaningful use incentive program is only one lever. CMS recently announced that the use of certified technology will be required to obtain the chronic disease management fee reimbursement.

Remarks and Review of Agenda

HITSC Vice Chairperson John Halamka thanked Reider, who is leaving ONC, for his many years of service and contributions. He summarized the importance of each of the items on the previously-distributed agenda. He predicted that 2015 will be a great year for interoperability. He asked for objections, corrections or additions to the summaries of the two previous meetings as circulated with the meeting materials. None were heard and he declared them accepted.

> **Action item #1: The summaries of the September 10 and October 15, 2014 meetings were accepted as circulated in advance of the meeting.**

Consolidated-Clinical Document Architecture (C-CDA) Version Migration and Cutover Findings

Charles Parisot, GE, spoke on behalf of EHRA. He explained that ONC had submitted questions to EHRA and EHRA surveyed its membership resulting in a 76% (n=26) response rate. He said that it is clear variants in EHR developer implementation approaches call for a very clear approach to this migration to ensure both forward and backward compatibility as new versions of C-CDA are developed. Addressing these asynchronous cutover issues is not specific to CDA but applies as well to V2 messages and FHIR. He went through a deck of detailed slides that summarized responses to specific survey questions. He pointed out that the introduction of a new C-CDA version (with new template ID version) needs to be planned with existing products to make them flexible receivers and minimally support senders of new C-

CDA version. A majority of the 26 members said that they would have a problem either distinguishing that the template IDs are different, or share the same root. Therefore, new programming will be required to support a new version in most cases, but it will not be difficult. To reduce compatibility issues between two versions, C-CDA R2.0 must be made backwards compatible. The EHRA members unanimously supported a statement that when comparing implementation costs to support on a new EHR system either only C-CDA R2.0 or both C-CDA R1.1 and C-CDA R2.0 be used. There is additional work to support both, but most implementers think it is not a major effort. He concluded that EHRA recommends that ONC engage HL7 and EHR implementers in analyzing C-CDA R 2.0 and minimizing version cutover challenges with a robust backward compatibility strategy.

Q and A

Wes Rishel asked about a window of time after data from which older versions would not be received. Parisot clarified that older version data would be received and displayed, but he recommended closing the window on importing data more than two versions past with versioning to be based on certification. Rishel asked about adding identified syntax for something to be ignored rather than treated as an error. A new certified version would be required to have that effect. Parisot agreed that products would have to be updated. Rishel said that all customers would have to go through an upgrade. He announced that he strongly supports a requirement for certification and compliance testing to include testing scenarios for handling of errors for wrong version sending. The extent to which older versions of CDAs are currently being used is a question. If the use is of low prevalence, then a much cleaner recommendation should be made. He proposed that issues of version compatibility start with V2 unless someone can make a strong case for hardship. Parisot offered to run another survey of EHRA members. Halamka requested staff to pursue such a request.

Eric Rose asked about problems with C-CDAs as human readable. Parisot explained that the majority of vendors agree to display data from older versions. However, applying an old style sheet to a newer version is a problem.

Briefing: S & I Framework Initiative Electronic Long-Term Services and Support (eLTSS)

Evelyn Gallego, S & I Framework, showed slides and talked about the eLTSS, which is a joint project of ONC and CMS. It will focus on identifying and harmonizing electronic resources that enable the creation, exchange and re-use of interoperable person-centered records by health care and community-based social service providers, payers and the individuals they serve. The information within these records can help to improve the coordination of health and social services that support an individual's mental and physical health. The program is based on the requirements of the CMS Testing Experience and Functional Tools (TEFT) in community-based long-term services and supports (CB-LTSS) Planning and Demonstration Grant Program created in the Affordable Care Act (ACA). The TEFT Grant Program is an opportunity to leverage health IT to help bridge quality measurement gaps specific to the experience and outcomes of care for adults receiving CB-LTSS. Demonstration grants were awarded to nine states in March 2014. CB-LTSS is defined as services provided to individuals who require daily living assistance due to physical, cognitive or chronic health conditions. TEFT establishes a person-centered eLTSS record to support the needs of CB-LTSS beneficiaries, not only as they receive support and services in their community but also as they move between institutional and non-institutional settings. Seven states will participate in the eLTSS Initiative, which will identify key client assessment domains and associated data elements that will inform the creation of a structured, longitudinal, person-centered electronic LTSS record. Under the auspices of the S & I Framework, the eLTSS record will be designed in such a way that it can be exchanged electronically across multiple CB-LTSS and institutional settings and with beneficiaries and payers. The standards identified for the eLTSS record will support interoperable

exchange with various information systems to include clinical information systems, state Medicaid and HIE systems and PHR systems. The content or data elements of the eLTSS record will be specific to the types of services rendered and information collected for CB-LTSS. Beneficiaries will be able to access the eLTSS record through their PHR systems, including the option of a state-identified PHR. The eLTSS Initiative will provide an infrastructure to standardize the exchange of the eLTSS record across community-based information systems. In the short term, the initiative will socialize the concept of the eLTSS record, define the information model necessary to support its adoption, and inform future efforts to integrate institutional LTSS data with CB-LTSS data. In the longer term, specification of standards for the eLTSS record will support and spur development and implementation of software and pilots that will inform refinement of these standards prior to their consideration for inclusion in future federal regulations, which include health IT certification requirements.

She continued. The S & I Framework phases (pre-discovery, discovery and implementation) will be executed from November 2014 through fall of 2015. The Pilot Phase 1 will run from fall 2015 through summer-fall 2016. Revisions to the eLTSS Implementation Guidance based on Phase 1 piloting will be re-tested during Phase 2 (fall 2016 through fall 2017). The revised Implementation Guidance based on Phase 1 Pilots will be presented to a standard development organization for balloting and publication. This timeline aligns with the CMS TEFT Demonstration Grant timeline that incorporates two pilot cycles for the seven states required to participate in the S & I eLTSS Initiative.

Q and A

David McCallie pointed out the great complexity of the project, which will be very difficult for vendors and users to standardize and implement. The HIE slide assumes something much more sophisticated than what is in actual operation in most locales. He proposed another approach in which the payer system hosts a smart app that plugs into the various domains so that it is not necessary to move information around. Gallego said that she is interested in innovative solutions. Her slides are intended to describe the conceptual model. She wants industry to come forth. Gallego and McCallie will work off-line on his proposal. According to Halamka, his organization uses something similar to what McCallie suggested.

Dixie Baker observed that the needs and challenges associated with eLTSS appear similar to those in the LTPAC industry. She recalled that there was another S & I Framework project on long term care. Gallego acknowledged that the eLTSS work will build on the results of the long term care project, which recently ended.

Kelly Hall emphasized learning from other efforts including PGHD. The patient must be in the center as an equal. Eisenberg commented on the app concept and agreed that it would be useful for coordinating among multiple entities. Regarding small data set management, he wondered who would define the set. Gallego responded that the answer to the question is one of the deliverables. Eisenberg reminded her not to exclude observation cases, those patients who are not admitted to hospital but are held for observation. John Derr announced that he is involved in the initiative and is recruiting other participants.

Standards and Technology Updates

Steve Posnack, ONC, reported that the 2014 Certification Edition release 2 test procedures were out for comments October 8 through November 7. Final test procedures are anticipated December 2014. Edge Protocol Testing development was led by NIST. The Alpha Release was completed October 30 and is available for public feedback (http://hit-dev.nist.gov:12080/ttt). Regarding the Test EHR Pilot Program, he thanked Meditech and McKesson Health Solutions for their completed work, acknowledged the work

of iPatientCare, Inc. and welcomed Cerner Corporation. Findings on the Open Test Method Pilots are being synthesized and will be made available in an upcoming workgroup meeting. FHIR work is proceeding.

Q and A

Halamka asked about a process for assessing and prioritizing the many S & I projects. Posnack explained that such a process is currently underway. McCallie inquired about the Direct Edge Protocol. He suggested that it may be overly limited to moving CDA documents around. Posnack suggested that they discuss it off-line.

S & I Framework Data Provenance Use Case

Julie Chua, ONC, and Jonathan Coleman outlined the use case. Chua said that the purpose is to establish a standardized way for capturing, retaining, and exchanging the provenance of health information. Participants will: define an initial set of provenance metadata and vocabulary; create technical specifications to standardize data provenance; and develop guidance for handling data provenance in content standards, including the level to which provenance should be applied. Candidate standards to date are:

- Cross Enterprise Document-Sharing (XDS)
- Simple Object Access Protocol (SOAP)
- Representation State Transfer (RESTful)
- HL7 Clinical Documentation Architecture Release 2 (CDA R2)
- HL7 IG for CDA R2: Data Provenance – Sep 2014 Ballot
- HL7 Version 2 Vocabulary & Terminology Standards
- HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
- HL7 FHIR DSTU Release 1.1 Provenance Resource
- W3C PROV: PROV-AQ, PROV-CONTRAINTS, PROV-XML
- HL7 Health Care Privacy and Security Classification System, Release 1
- HL7 Version 3 Standard: Privacy, Access and Security Services (PASS)
- HL7 Record Lifecycle Event Metadata using FHIR (project underway 2014)
- HL7 EHR Records Management and Evidentiary Support (RM-ES) Functional Model, Rel 2
- HL7 EHR System Functional Model Release 2
- HL7 EHR Lifecycle Model (2008)
- ISO/HL7 10781 EHR System Functional Model Release 2 (2014)
- HL7 Digital Signature
- ISO 21089 Health Informatics: Trusted End-to-End Information Flows
- Personal Health Record System Functional Model

Kelly Hall interjected that headers should include patients and their representatives. Provenance of actors in PGHD must be maintained. McCallie noted that the list of standards was a bewildering array. Chua said that the list represents nominations only. Halamka referred to the value of parsimony. Eisenberg agreed with McCallie, but said also that NIST 7804 on usability should be on the list. Coleman said that individuals knowledgeable with each of the nominated standards are being consulted. The number of standards will be reduced. Rose inquired about a list of critical data elements and user stories for use in consideration of standards. Coleman continued and described the use case. The complete set of materials includes data elements and stories. Scenario 1 describes simple provenance requirements when transferring health care data from a start point (sending system) to an end point (receiving

system). Scenario 2 includes a third party as a conduit or transmitter to transfer information from start point to end point. There may be use cases where it is important to know how the information was routed, as well as who originated it and who sent it. Scenario 3 uses a third party system to aggregate or combine information from multiple sources, either in whole or in part, to produce new health care artifacts. The new artifacts may contain information previously obtained from multiple sources, as well as new information created locally.

They presented questions tor which they wished the HITSC members to respond:

- Do the three scenarios in the use case, and the use case's identified scope, address key data provenance areas or is something missing?
- The use case is broad and spans a lot of challenges. Where in the use case should we start in terms of evaluating standards to meet use case requirements?
- Are there any architecture or technology specific issues for the community to consider?

Q and A

Halamka reminded the members that provenance is a HITSC priority. He said that the questions were quite complex. Rather than having a discussion during the meeting, he asked that they be assigned to the appropriate workgroups. Reider concurred, saying that workgroups or work teams are the appropriate places for discussions. Posnack indicated that the need for feedback was immediate. He preferred not to go through the workgroups. McCallie agreed with Halamka about the complexity of the questions, suggesting that the discussion be restricted to scenario #1. Coleman said that a lot of people with different interests are involved in the endeavor and they need to know what to address first. He suggested that they consider the second question. Rose pointed out that the capture of the data and audit functions must also be considered. Rishel talked about the importance of scoping. The impact on certification could be enormous. Scoping is a trade-off between perceived benefits and perceived complexity. It is better to error on the side of reduced scope. The use cases are highly technological and do not consider value in comparison to cost. Halamka said that the S & I Framework has many masters. A simple use case is preferable.

Other members shared their opinions. Rebecca Kush pointed out the relevancy of CFR 11 on tracking data. Acknowledging the length of the list of standards presented, she recommended that the operational model standard used in Germany be added. Eisenberg observed the importance of two use cases—direct clinical care and the secondary use of data for research and CDS. The latter requires data in addition to EHRs. Baker said that the approach described by Coleman is based on exchange rather than use of the data by clinicians. Use should be the primary focus. The purpose of provenance is to help clinicians determine the usefulness of the data. She recommended a total refocus of the project. Halamka told Posnack that although he (Posnack) wished to go forward, the committee can be most helpful by reducing the scope of the project and possibly proposing a better approach through one of the workgroups. Posnack indicated that he will consult with the chief privacy officer and other team members to decide how to proceed.

HITSC Workgroups and Operations Discussion

Posnack reported that staff has identified a major challenge in the new workgroup structure in that there is great potential duplication of effort and a high degree of staff hand-off and coordination is required on interdisciplinary questions. To meet this challenge, multi-disciplinary task forces will be formed as needed to address such questions and make recommendations on specific issues. The time-limited task forces will consist of a several members from workgroups whose disciplines will be applied to the question at hand. In terms of process, staff will identify questions for consideration and

assignment by the Steering Committee. He presented the following interdisciplinary questions which are of immediate import:

- In what ways can ONC evolve the S & I Framework to support current industry needs and those anticipated by the 3, 6, and 10-year milestones included in the Interoperability Roadmap?
- In what ways can semantic interoperability be best tested under the ONC Health IT Certification Program?
- With the 3-year Interoperability Roadmap goals in mind, what existing standards, if adopted nationwide, could provide cost efficiency or safety benefits, or both?
- In what ways or by what means should ONC measure standards use and interoperability for given purposes?

Through Q1 2015, the existing workgroups will provide feedback and recommendations on the Interoperability Roadmap and the 2015 Edition certification criteria proposed rule. In the second quarter, workgroups that have a unique or single scope of work will continue until they complete the work.

Discussion

McCallie expressed concern about members' time commitments. Halamka said that this is a construct that can be used as needed.

Public Comment

None

SUMMARY OF ACTION ITEMS:

Action item #1: The summaries of the September 10 and October 15, 2014 meetings were accepted.

Meeting Materials:

- Agenda
- Summaries of September 10 and October 15, 2014 meetings
- Meeting presentation slides and reports

Meeting Attendance								
Name	11/18/14	10/15/14	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14
Andrew Wiesenthal		X		X	X		X	X
Anne Castro	X	X	X	X		X	X	X
Anne LeMaistre	X			X	X	X	X	
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris	X		X		X	X		
Charles H. Romine		X			X			
Christopher Ross		X	X	X	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
Jacob Reider	X	X	X	X	X	X	X	
James Ferguson		X	X	X	X	X	X	X
Jeremy Delinsky	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
Keith J. Figlioli		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		X
Nancy J. Orvis			X	X		X		
Rebecca D. Kush	X	X	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	X
Steve Brown		X	X				X	X
Wes Rishel	X	X		X	X	X	X	X
Total Attendees	**20**	**22**	**22**	**24**	**22**	**24**	**21**	**23**