HIT Standards Committee
FINAL
Summary of the January 27, 2015 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.

Opening Remarks

Acting Deputy National Coordinator and Chairperson P. Jon White commented on the relevancy of the HITSC's work for interoperability. Information is essential for the delivery system reform that is underway.

Remarks and Review of Agenda

HITSC Vice Chairperson John Halamka noted the two major items on the agenda. He asked about revisions or corrections to the summary of the December meeting. Hearing none, he declared them approved as circulated.

> **Action item #1: The summary of the December 2014 meeting was accepted as circulated in advance of the meeting**

S&I Framework Task Force Update

Task Force Co-chairperson Stan Huff stated that the issue under consideration is whether the S&I Framework should continue. ONC staff organized a task force and gave it this charge: Is there a continued need for the S&I Framework (or an equivalent process) to advance standards and implementation specification development? If yes, in what ways could the current S&I Framework be improved or enhanced to better address identified industry needs? If no, what alternatives should be considered to address the identified industry needs? Co-chairperson Arien Malec reported that the task force members agreed to evaluate the key jobs to be done and, second, to assess the S&I relative to the agreed-upon jobs, and make recommendations on going forward and for a structure for ONC-organized engagement. He said that task force members had tentatively agreed that there are jobs to be done. Malec presented a list of the key roles that are gaps relative to the SDO mission:

- Support identified national priorities by: reducing optionality for existing standards; coordinating across SDOs and supporting SDOs; and facilitating consolidated artifacts (e.g., consolidated implementation guides)

- Support production use by: facilitating pilots and effective production implementation; feeding learnings back to SDOs (e.g., to further reduce optionality and clarify ambiguity); evaluating success of standards; and implementing guidance in achieving national priorities
- Facilitate effective Federal participation in SDOs
- Recommend needs for infrastructure and non-traditional SDO artifacts, for example, value sets, provider directory data sources (e.g., CMS NPPES modernization), and organizational identity assurance.

The task force is planning a virtual hearing for February 27. Phase 1 draft recommendations will be presented to the HITSC March 18.

Discussion

David McCallie talked about the importance of identifying a problem that needs to be solved. Malec acknowledged the need to take into account the application of resources such as the time and talent of those involved in these initiatives and their opportunity costs. McCallie wondered about the approaches of other industries, such as internet development. Malec responded that an upcoming listening session may be a venue for soliciting such information. John Derr said that S&I was very helpful to the long term care community. Wes Rishel stated that specific efforts within S&I have been helpful in solving problems. He suggested that the task force examine those products that made it into production, for instance, lab reporting, and why. He asked about the degree to which testing of interfaces is within the purview of S&I. Prototypes can take on a life of their own and subsequently change the definition of success. He gave the example of success in sending information without success with its receipt. He talked about the burden of certification and the need for better testing procedures. Malec said that Rishel's points were captured in the list. Leslie Kelly Hall pointed out that S&I included several underrepresented groups, such as consumers and long term care. Several members commented on the importance of establishing national priorities on which S&I would then concentrate efforts.

Data Provenance Task Force Recommendations

Task Force Chairperson Lisa Gallagher reminded the members that ONC staff had assigned a question to be answered: Given the community-developed S&I Data Provenance Use Case, what first step in the area of data provenance standardization would be the most broadly applicable and immediately useful to the industry? She showed slides and presented the recommendations as responses to three sub-questions.

Question #1 response

> The Use Case may be over-specified. The Task Force recommends that the Data Provenance Initiative should focus on: where did the data come from (source provenance); have the data been changed; can I trust the data.
>
> Begin focus from the perspective of an EHR - Provenance of the intermediaries is only important if the source data is changed. Therefore, begin focus from the perspective of an EHR, including provenance for information created in the EHR (source provenance) and when it is exchanged between two parties. The notion of who viewed, used or conveyed without modification along the way is not important for provenance, as long as the information was not changed.
>
> Clearly differentiate between communication and information interchange requirements and system requirements. For the purposes of this use case, start with the assumption that at the point for information interchange, the source provenance is good, complete and trusted. Address system requirements for provenance by looking at provenance data at the time of import, creation, maintenance, and export.

Consider FDA project, guidance and regulations - There are 12 requirements and use cases for the use of EHRs and eSource applications (e.g. patient reported information/eDiaries) requiring provenance described in an *eSource Data Interchange Document, FDA Guidance*, which includes a definition for the source and regulation for electronic records. If the content changes, the change should be considered a provenance event

Consider the implications of security aspects on the trust decision

Defining levels of trust would be a policy issue

Question #2 response

Address the Use Case in the following priority order:

- With exchange of data between EHRs
- At the point of origin or data creation in an EHR or HIE
- With the transfer of data from a PCD/PHR to an EHR system
- At the point of data creation in a Patient Controlled Device (PCD) or PHR

Clearly differentiate a set of basic or core requirements for provenance. Determine if Origination of the Patient Care Event Record Entry is in scope

- Address source provenance data within an EHR
- Consider those provenance events which an EHR would need for import, create, maintain, and export
- Define "source" (consider FDA definition)

Add CDISC ODM to the candidate standards list.

Consider any related requirements that may have implications (i.e., regulatory, program specific)

Question #3 response

Consider related work in HL7 projects, such as: CDA/C-CDA provenance, FHIR Provence Project, Privacy on FHIR Projects

In information interchange, the provenance of content should be lossless (retain integrity)

Discussion

Halamka noted his approval of scaling back the use case. Many members prefaced their comments with praise. Rishel referred to systems outside the EHR that provide source data and asked whether they are included in the recommendations. Gallagher said that the reference to source provenance includes those systems. One of the recommendations is to look at the FDA guidance, which includes patient devices. Rishel commented on problems with putting ODM into patient apps. He referred to the need for incremental progress given limited resources. He asked whether changes from change in character sets are considered a provenance event. Gallagher said that the recommendation is for S&I to consider this type of issue. She acknowledged that data shredding and creating a new composite document is another challenging topic for S&I to consider; the task force did not make specific recommendations on those topics. Jonathon Coleman, ONC, recognized that the issues are important ones and that the high-level recommendations will be taken to the next level.

Malec pointed out that the recommendations on losslessness and change were somewhat confusing. He asked about content reshuffling, saying that in sending information from A to B there is nearly always reshuffling to put information in the semantic shape and form that B understands. Gallagher replied that the task force recommended starting with simple exchange. She later asked Malec to submit language that would take his concern into account.

Eric Rose said that the recommendations must be feasible to implement. He wondered about a user action that is not a change, but is a new item. An example is problem list resolution. Floyd Eisenberg, a task force member, explained that this is one of the several situations that should be defined in the use case.

Dixie Baker asked about natural language processing and digital signature. Gallagher said that the recommendation is to look at existing standards of which natural language may be one. Additional standards can then be included. Regarding digital signatures, she pointed out other requirements for sources, all of which S&I should consider for core provenance requirements. Ann LeMaistre questioned the priority order on slide 11 and putting the point of origin first. Gallagher responded that each is a part of the same set of core requirements. Eisenberg interjected that ordering was not necessarily the best way to go, but the ONC instructions were to order them. Kelly Hall said that it should be acknowledged that much of the source data is from the patient, either via devices or in verbal reports.

Halamka summarized that the recommendations were to narrow use case scope. The goal is to identify provenance from the source of data to its ultimate use with integrity. He noted Malec's forthcoming language on losslessness, Rishel comments, and minimizing the importance of priority order as amendments. He asked for objections to the recommendations with the few modifications. Hearing none, he declared them approved.

> **Action item #2: The Data Provenance Task Force recommendations were approved with minor modifications to be submitted at a later time.**

Public Comment: None

SUMMARY OF ACTION ITEMS:

> **Action item #1: The summary of the December 2014 meeting was accepted as circulated.**
>
> **Action item #2: The Data Provenance Task Force recommendations were approved with minor modifications to be submitted at a later time.**

Meeting Materials:

- Agenda
- Summary of December 2015 meeting
- Meeting presentation slides and reports

Meeting Attendance						
Name	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X	X				X
Anne Castro	X	X	X		X	
Anne LeMaistre	X	X	X			X
Arien Malec	X	X	X		X	X
C. Martin Harris	X	X	X		X	
Charles H. Romine	X					

Christopher Ross	X				X	X
David McCallie, Jr.	X	X	X		X	X
Dixie B. Baker	X	X	X		X	X
Elizabeth Johnson	X	X	X		X	X
Eric Rose	X	X	X		X	X
Floyd Eisenberg	X	X	X			
James Ferguson	X	X			X	X
Jeremy Delinsky	X		X			
John Halamka	X	X	X		X	X
John F. Derr	X	X	X		X	X
Jon White	X	X				
Jonathan B. Perlin						X
Keith J. Figlioli		X			X	
Kim Nolen	X	X	X		X	X
Leslie Kelly Hall	X	X	X		X	X
Lisa Gallagher	X	X	X		X	X
Lorraine Doo	X	X	X		X	X
Nancy J. Orvis	X				X	
Rebecca D. Kush	X		X		X	X
Sharon F. Terry					X	X
Stanley M. Huff	X	X	X		X	X
Steve Brown		X			X	
Wes Rishel	X	X	X			X
Total Attendees	**25**	**22**	**20**	**1**	**22**	**21**