HIT Standards Committee
FINAL
Summary of the June 17, 2014 Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 58th 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. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves.

Opening Remarks

Chairperson Jacob Reider, ONC, thanked past Chairperson John Perlin for his services and presented him with a plaque. Perlin thanked the members and staff. Reider remarked that while the HITSC has been focused on standards for meaningful use, it must move to a broader view. HIT is broader than meaningful use. Not everything is relevant to meaningful use because not all providers are eligible for incentives. The FACAs are advisory; sometimes ONC staff asks for advice. ONC staff does not always take the advice. He went on to emphasize that regarding the S&I presentation, staff is not asking for the committee's approval. But he does want the members' perspective on priorities. Staff is looking for additional depth. He referred to the 10-year Vision to Achieve Interoperable HIT released several weeks ago. He wants feedback on which initiatives support or interfere with the plan. The assignments to the HITSC workgroups have yet to be finalized.

Remarks and Review of Agenda

Co-chairperson John Halamka also referred to the 10-year plan, saying that the S&I Framework should support that vision. But the initiatives should also support standards for Stage 3. There are things in the plan that are not in meaningful use. Having the right number of initiatives is important. He applauded Steve Posnack's appointment to head the Office of Standards and Technology. He asked about corrections of, additions to, or approval of the summary of the May meeting as circulated. Hearing none, he declared the summary approved.

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

Standards and Interoperability (S&I) Framework Update

Posnack and staff from the ONC Office of Standards and Technology showed slides and described the status of projects. Each S&I initiative focuses on a critical interoperability challenge through a process that includes:

- Development of clinically-oriented user stories and use cases
- Harmonization of interoperability specifications and implementation guidance

- Real-world experience and implementer support through new initiatives, workgroups and pilot projects
- Mechanisms for feedback, evaluation, and implementation testing

ONC supports this infrastructure with project management, subject matter experts, coordination tools, and other resources to accelerate work timelines. To date, 14 initiatives have resulted in technical solutions. Mera Choi pointed out a slide that listed initiatives and the related HITSC workgroups: Data Access Framework—Content Standards, Transport and Security Standards, and Architecture, Services and APIs Workgroups; EU and US eHealth Cooperation—Content Standards and Semantic Standards Workgroups; Blue Button Plus—Architecture, Services and APIs and Content Standards Workgroups; PDMP and HIT Integration—Content Standards and Semantic Standards Workgroups; Clinical Quality Framework—Semantic Standards and Content Standards Workgroups; and Data Provenance—Transport and Security Standards Workgroup.

Staff then talked about each of the active initiatives in great detail, summarizing the scope, content and technical work streams, output, and status, all of which were highlighted on slides. Evelyn Gallego described structured data capture (SDC). Two implementation guides (IG) are targeted for development based on SOAP/SAML and HL7 FHIR Profile standards. SDC SOAP/SAML IG consensus was achieved and the final SOAP/SAML IG was published March 18, 2014. Balloting was through the IHE Quality, Research and Public Health (QRPH) Framework as a Content Profile. The IHE Profile (Volumes I-III) was accepted through the QRPH committee on May 2, 2014. IHE profile is undergoing public comment until August 2014. The Open Issues form was posted to SDC wiki to track open items in the S & I artifact. The FHIR Profile IG will be balloted through HL7 starting in January 2015 in alignment with publication of HL7 FHIR Resources. The FHIR Profile IG was kicked-off in March 2014. The Project Scope Statement (PSS) was presented and approved at the HL7 May 2014 Working Group meetings in Phoenix. The primary HL7 workgroup sponsor for the PSS is Orders and Observations. The other co-sponsors workgroups are: vocabulary, patient care, clinical genomics, and clinical interoperability council. The scope of the PSS is to create an IG on the use of FHIR Profile(s) for SDC on the new Data Element resource and on the existing Questionnaire and Questionnaire Answers resources. These profiles will be used to meet SDC project objectives. The Patient Safety Event and Adverse Event SWG workflows are complete. The workflow to SOAP/SAML IG mapping is complete and one pilot is in committee. The Public Health Tiger Team (PHTT) addresses public health across Clinical Quality Framework (CQF), SDC, and Data Access Framework (DAF). Three use cases for SDC pilots were identified: cancer reporting, early detection, and case reporting. Data elements (semantics) have been identified for early detection.

Although Posnack had asked the members to hold their questions until the completion of the entire presentation, Halamka ruled that due to the level of detail in the presentations and the members' interest, questions would be entertained after the presentation of each initiative. In response to a question, Gallego said that they worked on SOAP/SAML first because the standards were available in the market and the standards were mature. FHIR will then be taken up.

Rebecca Kush talked about the need for alignment with research standards, some of which were completed in 2010. Although representatives from the research community are involved, there could have been more engagement. She referred to a meeting with IOM in May. Many stakeholders said that additional pilots are not necessary. The standards are ready.

McCallie expressed concern about forms definition language and ISO standards. Gallego said that the forms definition work is building off FHIR questionnaire resources. McCallie indicated that his recommendation of a simpler solution had not been accepted. He wondered whether other vendors were involved. Gallego said that the community took research and clinical needs into account and the

need for more granular data. She would love to have Cerner undertake demos, but not pilots. Although the standards are in place, there is no demand. McCallie told Posnack that the initiative time frame may not jive with the certification schedule.

Wes Rishel advised caution when moving beyond pilots. The real outcomes of pilots and demos are often overlooked. A committee with which he was involved did pilots that were deemed successful in sending information from SAMHSA providers to others. But although the sending worked, the recipients could not actually use the data. It is important to recognize the limitations and scopes of pilots. A systematic way of evaluating their results, such as a meta-analysis, is needed.

Dixie Baker said that she had been involved in the data capture profile years ago. Since it worked well, she wondered what will be gained by adding SOAP/SAML as another layer of complexity. Gallego responded that the community identified SOAP/SAML as the transport standards to be used so that interoperability could be addressed. The goal is to plug-and-play these standards. She will follow-up with Baker to identify the technical staff involved with the harmonization.

Leslie Kelly Hall asked about using DIRECT for transport, rather than mandating standards. Regarding questionnaires and PGHD, she wondered how to harmonize the patient as an author across multiple segments. Gallego replied that DIRECT was identified for transport. The community voted that DIRECT was not as feasible as other approaches. But DIRECT can be used in the pilots. The PCOR subgroup will deal with PGHD.

Jamie Ferguson commented on SDC and front-line workflows. Forms for data capture must be tailored to front line workers. Something that does not fit cannot be imposed. He asked for a description of the mechanism for getting input from front line workers. In addition, he observed that although slides said that several projects had been evaluated, he had not seen the reports. According to Gallego, a four-week workflow analysis was completed. Vendors, users, front line workers, safety managers and others were included. Ferguson indicated that the evaluations and publications on the pilots were insufficient. An overall evaluation in terms of the initial objectives of the projects should be conducted.

Gallego said that the initiative is leveraging and building on 11 1 79, but it is not a specific alignment. General semantics is out of scope; the focus is on syntax. For adverse events, the Common Format is used. A meaningful use starter set is being considered. LOINC and SMOMED are the attributes.

Stan Huff observed that across SDC, CDS. DAF and QM initiatives, there are fundamental infrastructure issues. Posnack said that they are working with HL7 groups on alignment around the same set of principles.

Kush commended that the SDC team for trying to please everyone. In trying to accommodate many standards, the staff goes to higher and higher levels. SDC has a distinct research component. The idea is to bring a form into place. The team lacks research expertise. Sometimes pilots fail because of the recipients not being prepared. Someone should map the core research data set and clinical care. She agreed with Huff about the need for a core data set.

McCallie agreed with Huff. The goal is to come up with a set to solve as many problems as possible with as simple a solution as possible. This project is unnecessarily complex. What is a spanning set of capabilities? Some candidates are FHIR, FHIR Profiles, and RFD. The latter can be expanded. ONC should reduce the number of problems to be solved.

Floyd Eisenberg said that much of this work is a repeat of what was done before by other organizations. The data are being used for different purposes. Are the intended recipients ready? CDC cannot receive vaccine adverse events reports. What is being done to get government agencies on board? Rishel emphasized that modularity of standards is not the same as optionality; or means and.

The data access framework initiative (DAF) in May launched Joint IHE/S&I DAF Gap Prioritization weekly calls to create a prioritization matrix of work efforts for 11 gaps identified in a white paper. A community-based volunteer technical sub-workgroup for DAF-Direct Transport solution option was launched. The IHE PCC DAF white paper will be released for a second public comment period to end in early July at the IHE Trial Implementation meeting. Publication to the IHE PCC technical resources is targeted for August 2014. Other launches took place in March and April 2014: Technical Sub-Workgroup for Data Element Based Access for both Local and Targeted Queries, for which an IG will be developed reviewing candidate standards and possibilities of a new FHIR profile, and the Technical Workgroup for Document Metadata Based Access for both Local and Targeted Queries. An IG for the latter will be developed from the analysis of the DAF white paper identifying both SOAP and RESTful solutions.

Arien Malec observed that staff is using a use case-based approach and standard-assembly approach. There was a white paper that identified 21 standards and included the appropriate solution. To address some of the concerns on population health, a different approach may be appropriate. The core underlying components should be identified. Some of the work of DIRECT Trust and others can be leveraged. Some standards are ready to go but the underlining capability for trust or inoperability is missing. The initiative is dealing with too much. The presenter, John Feikema, said that there is a very active DIRECT subgroup that recognizes the opportunity for addressing queries. It is looking at levering existing privacy and security standards. Acknowledging the validity of the comment on parsimony, he said that he will look into it.

McCallie spoke about opportunities for parsimony on the FACA side. The old HITSC power team, the new API Workgroup, and the recently appointed JASON Task Force must be coordinated. The emergence of FHIR and FHIR Profile plus security profiles presents opportunities. DAF should shift into how to use these emerging tools. Feikema responded that depending on pilot outputs, FHIR may be the recommendation. The S&I approach is to work in a community process to examine the available and emerging tools and to be open and transparent and bring the community along. McCallie disagreed with the utility of that approach, saying the focus should be on new technology that will work. He reported that Cerner has done many pilots with FHIR and he is confident that it is the way to go.

Referring to the JASON report, Halamka asked whether DAF is an API approach. Feikman expressed hope for the use of API approaches as a result of DAF.

Perlin commented on having an API approach in five years. API enables more innovation in having access to data. He recommended that the HITPC consider use cases of access in terms of certification. Standards may be available but something prevents their use. Remote versus local is becoming fluid.

Cris Ross wondered how the HITSC can help accelerate new technology. The S&I seems to be relying on a non-regulatory approach to accelerate the process. Perhaps more can be done. The new workgroup structure may further balkanize the work. Reider interjected that Ross seemed to be saying keep it simple and try to solve a few of the problems in the simplest way. He told the group to identify those targets and suggest how to better focus the efforts. Ross went on to say that vendors must comply with regulations. The game changed and the FACAs did not notice. Around the time of Stage 2, new standards became available, but they are not proposed for Stage 3. This is an important question to address in order to avoid a missed opportunity. Reider observed that the certification and meaningful use trains may not meet. The 2015 Edition specifies a regular ONC regulatory cycle to recognize new standards, but not to tie them forever to meaningful use stages. Halamka pointed out that the answer will not come today. FHIR, Restful and others may be coalescing to provide solutions to many of the initiatives.

Nancy Orvis expressed a desire to get the work done and to have a trusted framework as soon as possible. Kelly Hall referred to a cultural divide. The collaborative care model is new and requires new and more robust infrastructure. She suggested adding an innovation framework initiative with a natural evolution.

Referring to Ross' comment, McCallie said that certification should follow the market trends on interoperability. Regulation can smooth the rough edges. High levels of interoperability will happen when market forces demand them. Halamka reported that certified vendors cannot communicate without supportive market forces.

Next, the EU and US cooperation project was described. The Interoperability Workgroup is continuing development of the C-CDA CCD and the epSOS PS Comparative Analysis White Paper. Approval is expected by late July. In terms of workforce development, two skill maps were finalized and another began. The direct patient care domain (intermediate, basic, advanced, and expert) is scheduled for completion by mid-July.

Recent Blue Button Plus activities included a workshop at the June Health Datapolooza; discussions for coordinating with the ONC Consumer eHealth Team; and completion of RESTful (Pull) API, DIRECT (Push), privacy and security, and clinical content IGs. A RESTful API pilot is underway. Feikema said that regrouping is in effect. Baker inquired about the status of certification of apps to access EHRs. Feikema promised to provide the information at a later time.

Jonathan Coleman reported that PDMP and HIT integration work consists of outreach to standards organizations and PDMP technical experts and standards evaluation. The initiative is sponsored by SAMHSA. The initial standards evaluation with mappings to use case requirements was completed in April and the Gap Mitigation Plan was finalized May 13. The Solution Planning Workgroup launched two days later. A current standards landscape analysis was completed in June. Currently, staff is analyzing the technical feasibility, impact to stakeholders, and scalability for each proposed solution.

Coleman said that the data provenance use case was launched in June, following the launching of a tiger team in April. The team is assisting with detailed analysis of candidate standards for system functional requirements and interoperable exchange of data as directed by the initiative. Staff presented a Project Scope Statement to HL7, which was approved by the Community Based Collaborative Care (CBCC) Workgroup, the US Realm Task Force, and the Domain Experts Steering Division (DSES). TSC approval is being sought. The Notice for Intent to Ballot to HL7 is scheduled to be submitted in June.

McCallie reported that the HITPC Privacy and Security Tiger Team recently submitted recommendations on exchanging restricted behavioral health (CFR 42 Part 2) data. Is managing constraints a part of the use case? Coleman replied that they are still defining the use case. They expect to deal with part 2. McCallie informed him that the results will have a profound effect on vendor technology. Coleman said that up to 10 HL7 workgroups are deliberating on this topic. The goal is to support a broad range of use cases. Ferguson told Reider that provenance is the highest priority for initiatives.

Kelly Hall said that the patient should be included. There should be a tamper proof document for exchange in which provenance remains. Baker observed that the data segmentation for privacy project had been folded into provenance. How does that work? Coleman responded that the HL7 standard on data segmentation has a chapter that introduces provenance. Kush said that staff should consider a resource commonly used in research in which data carry audit trails. It is widely used around the world.

A staff member reported that clinical quality framework (CQF) staff is working on the harmonized specifications that will be used in pilots. Pilots being explored include: Chlamydia screening, Ischemic heart disease and anti-platelet use, radiology appropriateness of use, venous thromboembolism

prophylaxis, and cardiology appropriateness of use. The Health Quality Measure Format (HQMF) R2.1 package was approved for publication May 30. The Health eDecisions Knowledge Artifact (HeD KA) R1.2 was approved for publication on May 15. These other CQF artifacts are under development in preparation for the September HL7 Work Group meeting: HL7 Domain Analysis Model: Clinical Quality Common Metadata, R1 - US Realm; HL7 Domain Analysis Model: Health Quality Improvement, R1 – US Realm; Logical Model for Quality Improvement; and Clinical Quality Expression Language.

Eisenberg complemented the effort and said that his only concern is piloting, which is problematic for vendors when the models are not yet complete. Various committee members expressed support for the direction of CQF. Halamka spoke in favor of restricting measures to the data that are available. Reider interjected that ONC and CMS want HIT to support measurement, not a set of specific measures.

The presentation moved to community- or other agency-led initiatives. The PHTT charter was completed this month. The concept is to span several other initiatives. The PHRi education series was moved to PHTT. Resources for pilots are being requested. The team is coordinating with NCHS for profile integration and NLM to map data elements into SDC formatted data elements.

Someone from the staff said that the remaining projects—lab results interface, lab orders interface, esMD, and longitudinal coordination of care—use the S&I framework for coordination. They are mature and have strong followings. Information on the four was on the slides, but they were not individually described. For information, see http://wiki.siframework.org/

Kelly Hall and Derr commended the work on longitudinal coordination of care.

2015 NPRM Comment Update

Privacy and Security Workgroup Chairperson Dixie Baker reported that the workgroup had revised its responses to the NPRM based upon comments made at the May 2014 HITSC meeting, along with several clarifications provided by Posnack, and further deliberations on two-factor authentication, accounting of disclosures, and audit clarification within the context of ASTM E2147. Two changes in terms were also discussed and recommended. She referred to slides that listed the NPRM request, followed by the workgroup's response. Regarding the two-factor authentication, the workgroup said that the HITPC's policy recommendations are actionable, from a certification perspective, as the capability to require two forms of authentication can be tested functionally (for example, using the 800-63-2 LOA 3 functional specification). However, given the number of approaches that can be used in two-factor authentication for remote access, and the fact that authentication technology is likely to advance over the next three years, the Privacy and Security Workgroup (PSWG) cannot recommend a specific set of standards to use for this purpose. From a policy perspective, the workgroup noted that in today's environment, remote access may be difficult to define, as it is situational. For example, would EHR access using a mobile device within a hospital be considered remote access? Given this difficulty, the PSWG concluded that the level of assurance required for provider-users seeking remote access to EHR technology should be based on an assessment of the relative risk associated with the particular access approach used. Concerning broad adoption of two-factor authentication, the workgroup members are not aware of any meaningful use measures or other health care policy that would warrant a general requirement for a two-factor authentication capability. If the ONC decides to add such a requirement, the PSWG suggests that a product presenting proof of having passed a DEA audit of its two-factor authentication capability should be considered as having met the certification requirement for two-factor authentication for an EHR, but not necessarily for remote access. The PSWG noted that this can only be tested functionally. The PSWG also observed that these two use cases (e-prescribing of controlled substances and remote access) highlight the need for health care engagement with the NSTIC program.

Regarding accounting of disclosures, Baker said that the PSWG agreed with ONC's recommendation to remove the optional designation associated with the accounting of disclosures criterion. With the elimination of the complete EHR concept, such a designation no longer is necessary.

With regard to audit reports, the workgroup agreed with ONC's recommendation to remove the optional designation associated with the accounting of disclosures criterion. With the elimination of the complete EHR concept, such a designation no longer is necessary.

ASTM E2147 was updated a year ago, and the PSWG is not aware of any need to define query or any problems developers have encountered regarding query. Greater vendor input is needed to fully answer this question for the entire health care industry. The PSWG recognized that there is confusion in the market in understanding the Security Audit Logging concept and suggests that a broader reference to ASTM E2147 might serve well to help clarify any misunderstandings. Specifically, it recommended expanding the references to include at least section 5 which explains Security Audit Logging and describes the kinds of events that should be recorded in the audit log. In addition, the PSWG recommended that Section 7 be referenced in its entirety, rather than individually enumerating those parts of Section 7 that are not labeled optional. She noted that by citing all of Section 7, the labeled provisions still would be treated as optional.

Section 7.6 of ASTM E2147 specifies the types of actions to be included in the audit trail and should cover any type of action taken within an enterprise. In response to ONC's question regarding the inclusion of transmission as an action, the PSWG concluded that transmitting a record within an enterprise would require a copy and thus, is already addressed in section 7.6.

Baker reported that the PSWG believes it is quite feasible to certify EHR compliance with the ASTM E2147 audit log standard, and did not recommend ONC specify other actions in an updated standard for the 2017 Edition, or that ONC consider any additional standards. The workgroup also recommended modifications to the terms server authentication and automatic time-outs as used in the NPRN.

Discussion

McCallie, a member of the workgroup, said that he did not recall some of the discussion on time-outs. He did not want to create an artificial artifact for log off. Posnack questioned the need for certification to check for every particular. He suggested that for time-outs it would be sufficient to state that the desired outcome is blocking access to PHI. Baker and Halamka seemed to agree with Posnack. Halamka asked whether any member objected to acceptance of the recommendations. Hearing none, he declared them approved with the modification of the time-outs issue, which, according to Consolazio, can be reworded with the transmittal letter.

> **Action item #2: The recommendations of the Privacy and Security Workgroup on the 2015 NPRM were accepted as presented with a single modification of time-outs with no objections.**

Public Comment

Chris Chute, Mayo Clinic, asked for consideration of a new direction for the S&I. In its beginning, there was ARRA funding and a mistrust of SDOs. Now, the initiatives groups are working more closely with SDOs on standards. Despite the communication, more integration is needed. Consistent with the recommendations of the JASON Report, more work on an architectural infrastructure is needed. As a clinical research scientist, Chute said that research standards should derive from clinical data standards. A common data model is needed.

Gary Dickinson, CentriHealth, read a statement about his work on the S&I Simplification Workgroup. Beginning in 2011, the simplification group focused on 19 use cases to identify core components and

commonalities across use cases. The commonalities can be reused. A core component registry was established. Many agencies and organizations are involved. In 2014 the simplification method was approved as ISO 11969. Two use tools are in development.

Agenda Item Added

The next meeting is scheduled for July 16. Reider indicated that they will talk about what needs to be added to the S&I: Where is the market failing and what does government need to do? Halamka said that members seem to agree with the focus of the first three years of the 10-year plan. Reider announced that he wanted to poll members for the top S&I priority. The list below consists of one priority response per member. Some members named several, saying they were unable to decide on a single topic.

- Perlin – DAF
- Kelly Hall – provenance
- Ferguson – provenance
- Someone abstained
- Derr – LCC
- Someone – provenance and care coordination
- Halamka –DAF
- Baker – unable to decide on one
- McCallie – provenance
- Gallagher – provenance
- Eisenberg – provenance
- Someone – DAF
- Someone – CQF
- Ross – provenance
- Someone – provenance
- Malec – DAF
- Eric Rose – DAF
- Orvis – data access
- Rishel – asynchronous bilateral cut over
- Liz Johnson – no response
- Lorraine Doo – Blue Button Plus

SUMMARY OF ACTION ITEMS:

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

Action item #2: The recommendations of the Privacy and Security Workgroup on the 2015 NPRM were accepted as presented with a single modification of time-outs with no objections.

Meeting Materials

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

Meeting Attendance								
Name	**06/17/14**	**05/21/14**	**04/24/14**	**03/26/14**	**02/18/14**	**12/18/13**	**11/13/13**	**09/18/13**
Andrew Wiesenthal		X	X	X	X	X	X	X
Anne Castro	X	X	X	X	X	X		X
Anne LeMaistre	X	X		X			X	X
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris	X			X				X
Charles H. Romine				X	X			
Christopher Ross	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	X
Jacob Reider	X	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				X
Rebecca D. Kush	X	X	X		X	X	X	X
Sharon F. Terry	X	X	X	X	X	X		X
Stanley M. Huff	X	X	X	X	X	X	X	X
Steve Brown		X	X	X	X	X	X	X
Wes Rishel	X	X	X	X	X	X	X	X
Total Attendees	**24**	**21**	**23**	**24**	**23**	**21**	**23**	**24**