HIT Standards Committee
DRAFT
Summary of the July 16, 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 (three-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

Chairperson Jacob Reider, ONC, noted the occasion of the 59th meeting. He reminded the members that the charge of the committee extended beyond meaningful use to interoperability and exchange across the entire system.

Remarks and Review of Agenda

Co-chairperson John Halamka talked about the importance of each of the agenda items, one of which, provider directory, is an action item. He asked for acceptance of the summary of the June meeting. No objections, corrections or additions were heard.

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

ONC Data Update

Jennifer King, ONC, showed slides. For the 2014 reporting year, 2,823 EPs attested. Of them, 443 are new participants, and 972 attested to Stage 2. For the 2014 reporting year, 128 EHs have attested. Seventy are new participants and 10 attested to Stage 2. The time period is the first two quarters for EHs and the first quarter for EPs. She cautioned about drawing conclusion on early attestation data. Comparing Stage 2 attesters to Stage 1 attesters, urban and physician EPs are somewhat over-represented, with little difference in practice size. She also showed slides on objectives scores for EPs and EHs. To date in Stage 2, compared to Stage 1, a smaller number of vendors are represented.

Q&A

Halamka interjected that interpretation of the data will be used to inform the future timeline. Dixie Baker inquired about the characteristics of the vendors and market share coverage. King replied that most of the vendors covering Stage 1 attesters have certified for the 2014 Edition. Liz Johnson reported that her employer has 21 hospitals waiting to attest once problems with the website are resolved. King agreed that most likely other EHs have completed the process but have not officially attested and therefore are not captured in the totals. In response to a question from Halamka, King said that ToC and VDT functionalities are the most challenging. According to Halamka, the ecosystem requires more time to develop. Reider said that he cannot comment on the NPRM during the comment period. Referring to

King's slide on the objectives, Baker inquired about the difference between the summary of care record and the electronic summary of care. King responded that the objective has two parts and the thresholds are different—50% and 10% respectively. Halamka said that progress will inform later recommendations.

LTPAC and BH EHR Certification Recommendations

HITPC Certification and Adoption Workgroup Chairperson Larry Wolf reported on recommendations recently approved by the HITPC for voluntary certification of long term and post-acute care (LTPAC) EHRs and behavioral health EHRs. LTPAC and BH providers are not eligible for meaningful use incentives. Wolf showed slides and talked about the charge to his workgroup and the process by which it came up with recommendations. The workgroup recommended a five-factor framework for ONC to use when considering the establishment of a new certification program. The framework was then applied to LTPAC and BH, and workgroup members said that a voluntary certification program for LTPAC and BH was warranted. Certification criteria were recommended in four categories: for all providers, for LTPAC-setting specific providers, for BH-specific setting providers, and for some LTPAC and BH providers. He explained the following specific recommendations:

- Transitions of Care – Starting with the ONC 2014 Edition certification criteria, align and update the transitions of care voluntary certification criteria for LTPAC and BH with these criteria going forward;
- Privacy and Security – Starting with the ONC 2014 Edition certification criteria, align and update the privacy and security voluntary certification criteria for LTPAC and BH with these criteria going forward;
- LTPAC Patient Assessments – Support the use of ONC-specified HIT standards for a subset of patient assessment data to enable reuse for clinical and administrative purposes (e.g., exchange of the LTPAC Assessment Summary CDA document);
- BH Patient Assessments – Future work needed to identify standards to support BH patient assessments;
- Trend Tracking – Track national trends in LTPAC and BH health IT adoption, including use by functionality and by certification criteria; utilize EHR adoption definitions consistent with those used in ONC and CMS initiatives

Wolf informed the committee that other groups were dealing with data segmentation and certification for quality measures. Then he referred to considerations for some LTPAC and BH EHRs. The approach would be modular and voluntary. Functionality of value may vary by care setting depending on care delivery needs and scope of practice. LTPAC and BH providers have different needs; criteria should be evaluated independently for each setting. Recommendations in this category are based on ONC 2014 Edition certification criteria. There may be federal and state programmatic reasons for adopting certification functionality; in this instance, certification would serve as a baseline. Workgroup discussion focused on the added value of certification for these functions, but no consensus was reached.

Discussion

Halamka asked how vendors perceive voluntary LTPAC and BH certification: What are the benefits? Reider pointed out that all ONC certification is voluntary. He requested that the word voluntary not be used with LTPAC and BH certification. Rather, it is certification not tied to the incentive program. ONC staff hears that vendors perceive certification as beneficial to their marketplace. Staff has heard from several companies. They are particularly interested in standardization. They are looking for guidance.

John Derr reported that LTPAC providers and vendors are overwhelmingly enthusiastic about certification. They need it for transitions of care. Payment models must be changed. He talked about the need to educate hospital managements and EHs about the LTPAC industry.

David McCallie commented that the objectives of certification programs should be carefully considered. Standardization of patient assessments must be clinically driven. Regarding data segmentation, he noted that the receivers must be able to manage these data.

Wes Rishel said that the single issue that predicts interoperability is economic need on both sides. Changes in payment systems are leading to those needs. He suggested that Wolf identify a specific sector and develop a use case. If transition of care is the most important use case, the economic factors should be clarified. He went on to ask Wolf what standards he was referring to when he talked about standards absent proof of their effectiveness through pilots. Wolf referred to the Impact project in central Massachusetts. Project staff expanded the CCDA to help post-acute care providers. It was piloted as a community experiment with dozens of providers.

Halamka observed that the meeting was running behind time.

Andy Wiesenthal inquired about a comparison of the recommendations with existing standards and criteria in order to know what needs to be developed and piloted. Wolf acknowledged that although the workgroup did not undertake such a comparison, it would be necessary to do so. Halamka reported that Larry Garber has conducted such an analysis. Wolf said that CMS and others are working on standardization. Wiesenthal pointed out that standardization of content and an analysis of whether an EHR can use the content are different.

Derr mentioned a new CMS grant intended to standardize state Medicaid requirements.

Data Segmentation Recommendations

HITPC Privacy and Security Tiger Team Chairperson Deven McGraw explained that the team had been directed to consider privacy and security certification enhancement pertaining to BH for both meaningful use and non-meaningful use providers. She described the issues leading to the directive, such as the concern with granular consent, coordination of behavioral health and medical care, and specific consent requirements for behavioral health services. The team obtained information on the S & I Framework DS4P project, which has potential for segmentation and disclosure of records covered by 42 CFR Part 2. The team came up with a 4-level glide path for recipients of Part 2-protected data. In level 0, the current state, Part 2-covered data are not provided electronically to general health care providers. The status quo is to share Part 2-covered data via paper, fax, etc. At level 1, document-level sequester, the recipient EHR can receive and automatically recognize documents from Part 2 providers, but the document is sequestered from other EHR data. A recipient provider using DS4P would have the capability to view the restricted CCDA (or data element), but the CCDA or data cannot be automatically parsed, consumed, or inter-digitated into the EHR. Document level tagging can help prevent re-disclosure. At level 2, a local use only solution, the recipient EHR can parse and extract data from structured documents from Part 2 providers for use in local CDS and quality reporting engines, but data elements must be tagged and/or restricted to help prevent re-disclosure to other legal entities through manual or automated reporting or interfaces. This would allow the data to be used locally for CDS but would not require complicated re-disclosure logic for the EHR vendor (i.e. Processes around re-disclosure are not well-defined). At level 3, EHRs for general use and sharing advanced metadata and re-disclosure, the recipient EHR can consume patient authorization for re-disclosure from a Part 2 provider and act on such authorizations at a data level. At a minimum, the recipient EHR would need to make the user aware of whether additional Part 2 consent is required before re-disclosing any particular data element to another legal entity, and allow recording of patient authorization for re-disclosure at the data level. Processes for re-disclosure are well-defined. Next, McGraw reported on the specific recommendations approved by the HITPC:

- Ideally for Stage 3, include level 1 send and receive functionality in voluntary certification program for BH providers. The BH EHRs must be able to control which recipients can be sent Part 2-covered electronic documents.
- Ideally for Stage 3, include level 1 receiver functionality as voluntary certification criterion for CEHRT. Only recipient providers interested in being at level 1 would request capability from vendors. Moving from sender status quo – 0 – requires level 1 capabilities for sender and at least level 1 capabilities for recipient.
- Level 2 and 3 are beyond MU 3. However, progression is less likely to occur if we don't lay the foundation for moving from level 0 to level 1 for both BH, EP and EH EHRs.

Other recommendations pertained to pilots, guidance, and education of providers and patients. Finally, she presented the recommendation asking the HITSC to answer these questions:

- Is DS4P or any other standard mature and feasible enough for BH EHR voluntary certification, and if so, at what level of granularity?
- Is DS4P or any other standard mature/feasible enough for general EHR voluntary certification, and if so, at what level of granularity?

Discussion

Arien Malec referred to slide 10, saying that the expectations for EHRs are not clear. Can the certification requirements be operationalized for receiving EHRs? For example, can warnings of the content of the document be generated? McGraw explained that in the pilot the entire document was tagged. At the receiver end, the document cannot be opened and read without the technology. But even when opened and read, not much can be done with it. One purpose of the recommendations is to lay a foundation and encourage development. Malec said that the approach of the pilot left what to do with the document unspecified.

McCallie, a member of the Privacy and Security Tiger Team, told Malec that although the higher levels are arbitrary, they may be achievable. They await better standards in order to do something with the tagged data. The document is received with signals that it contains data that cannot be pulled into the record. It is a sequestered step. Malec commented that many issues had been raised.

In response to a question from Halamka, McGraw said that she wanted the topic assigned to a workgroup. Providers need to communicate with BH providers; the lack of communication has an adverse effect on care. Although SAMHSA is examining the issue, its officials are locked in by statutory language. The CFR Part 2 re-disclosure requirement cannot be eliminated absent new legislation. She was not aware of such legislation being proposed.

Eric Rose commented that restriction on communication with BH has been an issue throughout his 20-year practice. He asked about a document that contains information that the recipient provider already has in her record. In his years of practicing medicine he has never received written information on a patient from a BH provider so anything will improve care. McGraw indicated that she hoped SAMHSA officials will differentiate information from a BH provider that is protected and information from a BH provider about non-sensitive conditions.

McCallie recalled that a SAMHSA official had said that if a receiver already has the information in the document, the restrictions do not apply. McGraw observed that the environment is confusing.

Wiesenthal talked about his experience at Kaiser Permanente, an integrated system. Legally restricted components of the record are sequestered. All of the users of the EHR know that something is sequestered and if necessary can break the glass. The issue of passing information down the line is not relevant. More and more integrated systems are being formed. Sequestration of information is very dangerous in an environment in which there is increasing reliance on CDS and alerts.

Lisa Gallagher asked about future work of the HITPC on data segmentation. McGraw responded that at the moment nothing is in the queue. If and when SAMHSA issues guidance, there may be more deliberation in the HITPC.

Rishel commented on the usefulness of the term inter-digitated to mean taking in data and using combined data for various purposes. He asked Wiesenthal whether the Kaiser Permanente system can temporarily de-interdigitate the data for use by CDS or another function. Wiesenthal had left the meeting and was not available to answer. McGraw suggested that Rishel's question be taken up by a HITSC workgroup.

Halamka said that standards for data segmentation will be assigned to a workgroup.

Provider Directory Update

NwHIN Power Team Chairperson Dixie Baker reported on the team's deliberations on provider directories. The HITPC Information Exchange workgroup made recommendations pertaining to EHR systems having the ability to query external provider directories to discover and consume addressing and security credential information to support directed and query exchange as well as the ability to expose a provider directory containing EPs and EHs addresses and security credential information. Information Exchange Chairperson Micky Tripathi met with the team to explain the workgroup's recommendations and to request advice from the NwHIN Power Team. Baker showed a slide that summarized the key points made by Tripathi. The team eventually concluded that no existing provider directory standard is ready to become a national standard. Although IHE HPD+ is a good start, proof in the marketplace is needed. Leveraging the National Provider Identifier (NPI) directory to provide Direct addresses may be an interim path forward. Exploration of other simple approaches, such as FHIR-based approaches, should be explored. Determining whether mutual authentication is a risk-based decision should be up to the directory service provider. Although mutual authentication is built into the HDP+ spec and is available if required, the team agreed to remain silent on the topic.

The NwHIN Power Team recommended:

1. Based on our assessment of the functional requirements for querying provider directories, we know of no standards that are sufficiently mature and implementable to become a national standard. IHE's HPD+ profile is a good start, but needs to be proven within the marketplace.
2. We recommend that ONC encourage the exploration of other simple approaches for implementing the required functionality, such as working with CMS to harmonize its RESTful directory approach with FHIR.
3. We note that the federal government has already implemented a database of national provider identifiers (NPIs) and suggest exploring the possibility of providing the capability to capture Direct addresses within this database and making the information publically accessible through a service interface.

NwHIN Power Team Co-chairperson McCallie said that the team looked for a simple approach. The team members were puzzled by the recommendation on managing secure addresses, which Direct makes readily available.

Discussion

Halamka said that he has experience with a RESTful approach and it worked well.

Rishel suggested that exploration of the NPI include its effectiveness. In the past the NPI reportedly contained many duplicates and some types of providers were not included.

Halamka called for action on the three recommendations, which he repeated. He asked about objections. Hearing none, he declared the recommendations on provider directory approved. The recommendations will be officially sent to ONC with a transmittal letter.

> **Action item #2: The recommendations presented by the NwHIN Power Team on provider directories were approved without objections.**

Standards and Technology Update

Steve Posnack, ONC, gave the status report on the many S&I initiatives. He began with a slide categorizing them as active, community or other agency led, or inactive. He showed slides to summarize current and upcoming SDO engagement for these projects: Structured Data Capture, Data Access Framework, Data Provenance, Blue Button Plus, EU-US eHealth Cooperation, Clinical Quality Framework, PDMP-HIT Integration, Cancer Registry, Laboratory Orders Interface, Laboratory Results Interface, Electronic Submission of Medical Documentation, Longitudinal Coordination of Care, and Public Health Tiger Team.

Turning to the certification program, he reported that five testing labs are in operation. CCHIT withdraw from the certification program in January 2014. There is no evidence of back logs. He announced a new project to involve stakeholders in testing. In the past although anyone could submit testing materials, no one did. Consequently all of the materials in use were developed by ONC and NIST. Vendors and providers complained about the testing materials. Staff decided to expand opportunities for stakeholder involvement. Therefore, ONC is launching a new pilot project to invite the industry to contribute materials for test methods. This is an opportunity for industry to apply its field experience. The pilot project will focus on two certification criteria yet to be selected. Results are expected by October.

Halamka asked about the interest of the vendor community in this effort. Posnack acknowledged that vendors are not necessarily interested in ownership. ONC staff wants to engage developers and to improve test procedures. Halamka said that this effort has possibility for increasing efficiency.

Q&A

Malec indicated that he was pleased with this approach. He wondered how it could lead to a different certification process, citing examples of potential improvements. Posnack said that this pilot will involve the community in the scope of testing. The community will then be more aware of processes and will experience fewer surprises.

Leslie Kelly Hall talked about the need to institutionalize patient inclusion in ongoing projects. Posnack reminded her that the S&I Framework is an open process. He asked her to identify groups to involve. Kelly Hall told him that she would discuss the topic with him off line. Inclusion must be more mindful and not depend on individual suggestions to staff.

McCallie announced that he agreed with Kelly Hall. Although S&I may be open, that does not mean that the right people show up to participate. A mechanism to ensure adequate review is needed. He reported that he had been asked to audit projects that were in process, but had missed the point. Open is not the same as good. Reider said that he agreed although a closed process does not assure quality either. Government's role is to coordinate and collaborate. He appealed for engagement. He reminded them that what Posnack described for testing procedures is post regulations. There are numerous opportunities for more participation and openness all along the line.

Rishel observed that although the S&I work is open, it is also constrained.

ONC Announcements

Reider announced the new HITSC workgroup structure, which will consist of the following: Steering Committee, chaired by Halamka; Semantic Standards Workgroup, co-chaired by Jamie Ferguson and

Becky Kush; Content Standards Workgroup, chaired by Wiesenthal; Transport and Security Standards Workgroup, chaired by Baker; Architecture, Services and APIs Workgroup, chaired by McCallie; Implementation, Certification and Testing Workgroup, co-chaired by Johnson and Cris Ross. Reider said that the chairpersons and co-chairpersons were selected from among persons who were nominated or self-nominated. Co-chair appointments have yet to be finalized. The workgroups will be phased in through November at which time the structure will be fully operational. Memberships will be announced in August. The chairpersons, co-chairpersons, and staff will make the selections. He talked about having diversity of perspective, representation, race, ethnicity and gender. Reider distributed a document delineating the charges of the workgroups. The Steering Committee is responsible for reviewing HITPC recommendations, defining the standards issues posed by the recommendations, and assigning issues to the appropriate workgroups. It is responsible for assuring that all stakeholder interests are integrated across the workgroups.

McCallie talked about the importance of coordination. He referred to work on FHIR, which affects transfer, semantics and content. Reider acknowledged the importance of coordination, which falls within the purview of the Steering Committee.

Public Comment

David Tao, ICSA Labs and a participant in S&I Framework projects, commented that in the beginning many sign up, sometimes as many as 100 individuals for a project. Maybe 10% attend meetings. But few have time to be actively involved. There are a great many S&I projects. He asked for a retrospective analysis on participation to inform potential decisions about narrowing the scope of S&I. The analysis should examine the extent to which persons with appropriate technical skills are involved.

SUMMARY OF ACTION ITEMS:

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

Action item #2: The recommendations presented by the NwHIN Power Team on provider directories were approved without objections.

Meeting Attendance								
Name	**07/16/14**	**06/17/14**	**05/21/14**	**04/24/14**	**03/26/14**	**02/18/14**	**12/18/13**	**11/13/13**
Andrew Wiesenthal	**X**		**X**	**X**	**X**	**X**	**X**	**X**
Anne Castro		**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**	**X**		

Christopher Ross	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	X
Jacob Reider	X	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
John F. Derr	X	X	X	X	X	X	X	X
Jonathan B. Perlin		X	X	X	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			
Rebecca D. Kush	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	X	X
Wes Rishel	X	X	X	X	X	X	X	X

Total Attendees	**21**	**24**	**21**	**23**	**24**	**23**	**21**	**23**

Meeting Materials

Agenda
Summary of June 2014 meeting
Meeting presentation slides and reports