HIT Standards Committee
DRAFT
Summary of the August 22, 2013 Virtual Meeting

ATTENDANCE

The following members attended the meeting:

- Dixie Baker
- Anne Castro
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- James Ferguson
- Lisa Gallagher
- John Halamka
- Catherine Hong for Steve Brown
- C. Martin Harris
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Kamie Roberts for Charles Romine
- Eric Rose

The following members were absent:

- Jeremy Delinsky
- Keith Figlioli
- Rebecca Kush
- Anne LeMaistre
- Nancy Orvis
- Christopher Ross
- Sharon Terry
- Andrew Wiesenthal

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 50th 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 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.

Remarks

Farzad Mostashari, National Coordinator, remarked on his decision to step down. He thanked the members, several of whom had written about him upon hearing of his announcement. He reminisced about his experiences in public health and federal service and what he had learned. One learning was to be oneself and not be afraid to show passion. Linking passion in the private and public sectors can contribute to successful endeavors. He thanked the committee and ONC staff for their commitment and work. Several members of the committee thanked Mostashari and praised him highly.

Chairperson John Perlin read a resolution on behalf of the HITSC recognizing and thanking Mostashari for his leadership and public service, pragmatism, and empathy in advancing the HIT ecosystem to improve the nation's health. He asked for objections and, hearing none, declared the resolution adopted.

> **Action item #1: A resolution in recognition of the leadership and public service of Farzad Mostashari was adopted unanimously.**

Review of the Agenda

Chairperson Perlin referred to the summary of the July meeting, which had been circulated with the meeting materials. He noted that Dixie Baker had an amendment. Baker said that she had forwarded the mark-up to Consolazio. Her amendment was a correction pertaining to a comment she had made during the discussion following the update from the Implementation Workgroup (p.5). In lieu of outside-the-box solutions, the reference was both integration and usefulness of these data in reference to a number of criteria and pragmatic applications. Eric Rose asked that the categorization scheme referenced in a comment made by him be corrected to PDMs categorization. Perlin referred to grammatical improvements that he had submitted. Perlin asked for approval of the summary with the above changes. No objections were heard.

> **Action item #2: The summary of the July 2013 HITSC meeting was approved with two corrections.**

Comments

Vice Chairperson John Halamka commented on several of the agenda items, saying that Liz Johnson's report was an opportunity for the committee to get feedback on the extent to which the recommended standards actually work in implementation. The NwHIN Power Team's report will provide recommendations on transport standards.

Implementation Workgroup (IWG) Update

Chairperson Liz Johnson presented the key findings compiled by ONC staff on the implementation and usability hearing convened July 23 by the Implementation, Certification and Meaningful Use workgroups. Nineteen workgroup members attended. A presentation from a team of human factors experts described findings from site visits to nine vendors to understand current UCD process and challenges to incorporating usability into the product development cycle. Vendor UCD processes vary from none (focus on customer requests only) to basic (understand UCD concept but unable to integrate) to rigorous application with efficient testing and extensive infrastructure. Confusion exists between feature and function versus useable workflow. Timing of new releases limits end user design input. Vendors reportedly were of the opinion that private industry should be allowed to drive UCD. EP and EH panelists most frequently mentioned challenges related to actual Stage 2 requirements, such as patient access; view, download and transmit; summary of care; and quality measures. Most expressed concern about the timeline for completion of the advance work and meeting the attestation window. Another key theme was that the use of HIEs is proliferating, but the functionalities are diverse. Questions exist around how the vendor products will stitch together, particularly related to secure transport, as well as to the extent that

vendors are working together. Regarding usability, flexibility in design can create conflict with the goal of use of standards (.e.g., transport, e-measures). Usability should be guided by understanding the users, the workflow, and the context of work. Current testing and therefore design often reflects measure criterion compliance. Insufficient, inconsistent formal data are available on implementation and usability. Research is needed. Additional certification criteria for testing are not the answer; instead, future surveillance activities of the ONC should be considered.

She presented three recommendations, saying that each of the workgroups will likely generate additional recommendations:

- Promote usability by aligning testing and certification with plausible workflows
- Identify industry standards for EHR elements to promote safety and usability (i.e. TALLman letters)
- Establish normative time to implementation and meaningful use attestation from rule issuance

Carol Bean, ONC, reported on the 2014 Edition test scenarios, which staff and the workgroup have been working on since 2012. The scenarios are intended to: align with support for usability; ensure that data can be used within and across systems; make testing more efficient and consistent; and align testing with plausible clinical workflows. In 2013, with IWG support, ONC has: developed a proof of concept including a draft test scenario; piloted a draft test scenario; and outlined plans for developing further scenarios. Bean explained that the plan for developing further scenarios is based on a clinically plausible workflow that: follows a patient from contact with an EP or EH through care and follow-up; follows an EP or EH from patient care through public health and clinical quality measure reporting; and includes all of the 2014 Edition EHR Certification Criteria. Limited pilot testing suggests that scenario-based testing may reduce testing time as much as 50 percent, as well as simplify the set-up. The workgroup will review and advise on the workflow outlined by staff. She emphasized that the workflow depicted on the slide is only one possible workflow for testing, not the only way a workflow could link the capabilities tested. Five draft test scenarios will be posted for comment September 6.

Discussion

Bean clarified that the posting scheduled for September 6 will not be all inclusive of what would be required for using the scenarios. The public health reporting and quality measures will come out later toward the end of the year.

In response to a question about feedback on the certification process in terms of usability, Johnson said that the hearing did not specifically invite testimony from vendors.

Mostashari commented on two advantages of the scenario-based testing. One is that by eliminating the re-entry of patient data, the burden effort is reduced. The second, and greater, advantage is the gain in confidence that data collected in one part of the workflow are used efficiently throughout, without daily duplicate data entry.

Baker referred to the hearing and pointed out that several participants talked about having to hand-build interfaces for data exchange. Since considerable expense is involved, standardization of interfaces is needed. She went on to report that a participant had said that it is easier to implement view integration than exchange of data. View is much safer from a security perspective because it does not involve actual data flow and replication of data. These are important considerations in recommending standards for query, something very important to the physicians. The committee should consider the utility and ease of implementation for the view as query as well as the exchange of data.

Halamka talked about clinicians believing that copies of data viewed must be saved in the event of being sued. Policy guidance may be needed. Wes Rishel suggested that the topic be discussed at another time.

Scott Purnell Saunders, ONC, described the test scenario as consisting of two major sections—medical and administrative. The clinical section consists of five categories of testing criteria. The first is clinical intake: A patient presents and data are obtained and entered once. The second is transition of care and clinical reconciliation. The third is care ordering. Section 4 is care result and the fifth is the post-care section, including the patient list, admissions, and other providers. The administrative section is in a development phase and will be completed when the clinical section is completed. Since the latter is more technical in nature and requires more work, staff wants to have it completed first. The bucket list will be available and disseminated in early September. The feedback from the pilot was positive. Testing took about a week and the burden was reduced from the previously used procedures.

Rishel declared that although he approved of scenario-based testing, he was concerned that adopters of Stage 2 software need to begin testing cycles in the next few weeks. He asked how many vendors will have the option to use these new testing procedures. Bean replied that some vendors have completed certification. Some of the pilot test vendors had passed the certification criteria. They were enthusiastic. Vendors and developers are taking a slightly different approach for Stage 2, perhaps a more cautious and measured approach to certification this time. A large number of vendors and EHR technologies that have the potential to use the scenario-based testing will benefit from doing so. The ability to designate their products as having gone through scenario testing actually gives them something to market.

Eric Rose cautioned about scenario-based testing becoming a backdoor way to introduce new certification requirements. He said that ONC should check with the vendors to determine whether they think there is anything in this scenario that implies a requirement over and above what is outlined in the regulations. Bean acknowledged the validity of this point, saying that is one of the reasons for moving carefully. Ultimately, a library of scenarios for different workflows would be useful. Perlin said that certification could lead to things that are certified but are not necessarily compatible. Halamka stated his approval of scenario-based testing.

Noting the time, Perlin asked members to be brief. Rishel talked about a delicate balance to avoid defining the architecture of EHRs while making data gathering easier. It is worth using the full legal process to move certification in that direction.

Floyd Eisenberg said that scenario-based testing would be very helpful as well in developing and testing the ECQM and other information required for them. Rather than thinking of the quality measure reporting as a scenario, perhaps the development and testing of the measure content ought to be managed the same way to avoid duplicate entry and hardwiring. Perlin told Bean to take note of Eisenberg's comment.

Stan Huff commented that measures and other functionality certification stifles innovation and has not improved quality of patient care. If people are held accountable for the outcomes and sharing data, then they will improve functionality through innovation and other means.

NwHIN Power Team Update

Chairperson Dixie Baker announced that the following new members have joined the team: Jitin Asnaani (AthenaHealth); Keith Boone (GE Healthcare); Kevin Brady (NIST); Keith Figlioli (Premier); and Josh Mandel (Harvard Medical School). She reminded the members that following the presentation of preliminary recommendations on whether ONC should consider enhancing the current portfolio of transport standards to support consumer exchanges for stage 3 meaningful use and beyond by considering Blue Button Plus (BB+), HL7 Fast Healthcare Interoperability Resources (FHIR), and RESTful Health Exchange (RHEx) to identify industry trends and emerging standards, the HITSC had directed the team to expand its scope of applicability beyond consumer-provider exchanges to include any health information exchange that can be supported using a RESTful service. The team solicited input from the Privacy and Security Workgroup and the Consumer Technology Workgroup. Baker described in detail the standards reviewed and the results, saying that two levels of specifications emerged. Lower-level building blocks

consist of: HTTPS – secure web-based transport; OAuth2 – authorization of third-party applications; OpenID Connect – sharing of identities and attributes; and FHIR – simplified, structured content for RESTful exchange. Higher-level applications are: BB+"Pull" – consumer or authorized third-party query and retrieval of health data; and RHEx – demonstration prototypes of RESTful health exchanges. As previously stated, the team concluded that Secured RESTful transport (HTTPS) + OpenID Connect authentication + OAuth2 authorization + FHIR health care content lead to a safe and appropriate set of standards to use as building blocks for more complicated health care applications.

The Privacy and Security Workgroup, whose membership includes persons with direct experience with the standards, added a recommendation for IHE Internet Use Authorization to leverage NwHIN-recommended standards to address use cases in which a resource service needs to make additional access-control decisions beyond those made by the OAuth2 system (e.g., data segmentation for privacy, emergency break-the-glass override, role-based enforcement, purpose-of-use decisions) and uses JSON Web Tokens (JWT) and optionally SAML tokens, with well-defined user-context attributes. A draft for public comment was published in June 2013.

The Consumer Technology Workgroup observed that OAuth2 is dependent on portal identity management. BB+ "Pull" redirects patient authentication to the provider's portal authentication service. Therefore, OAuth2 authorization of a requesting app depends upon the strength of the portal's identity management policies and technology. Providers need to make sure that the level of assurance provided by their portal identity management approach is sufficiently robust.

She presented the consolidated recommendations for the committee's action:

> Secured RESTful transport (HTTPS), OpenID Connect, OAuth2, and FHIR can be used together to build safe healthcare applications: We recommend ONC support the development and piloting of these standards as candidate building blocks for healthcare applications. BB+ "Pull" holds potential as a national implementation specification for future meaningful use editions, but further development and piloting are needed. RHEx Project is a useful demonstration of how these standards can be used together to support robust but simple healthcare exchange.
>
> IHE IUA profile appropriately constrains and structures OAuth2 tokens to support sharing of user-context assertions such as "purpose of use" and is recommended for use in environments that require coexistence with existing profiles based on IHE constrained user-context assertions.
>
> BB+ concept of implementing a Registry Service to recognize two types of registration – "trusted" and "open" – assumes policy that has not been established and implies a level of app "trustworthiness" that may not be justified: we recommend ONC ask the Privacy and Security Tiger Team to address the questions of whether "trusted registration" with a Registry Service should be required for BB+ "Pull" applications, and if so, what should "trusted" entail.

She summarized the recommendations: Secured RESTful transport (HTTPS) + OpenID Connect authentication + OAuth2 authorization and, as applicable, the IHE Internet User Authorization (IUA) Profile + FHIR health care content provides a safe and appropriate set of standards to use as building blocks for more complicated health care applications.

Halamka indicated that the recommendation was an action item. Perlin agreed. Baker asked whether Co-Chair David McCallie had a comment. He did not.

Discussion

Jamie Ferguson said that although he supported the intent of the recommendations, the conclusion about FHIR was overly optimistic. There is no evidence at this time to support the recommendation on FHIR, though he supports moving in that direction. Baker quickly agreed that proof was lacking, saying that

"can" in the first line could be changed to "may." McCallie observed that FHIR does not address safety; it leverages other standards. Baker suggested deleting "safe and." Ferguson indicated support for pilots, demonstrations, and evaluation.

Rishel said that in addition to recommending the necessary piloting for safety issues, they should urge ONC to establish a deadline to allow for use in Stage 3. There is enthusiasm for FHIR now, but that enthusiasm may wane later in the cycle. He was concerned about implying that assurance should be applied to apps. There is a growing set of apps that consumers use without any level of assurance. The user makes the links and it is acceptable to exchange these data. The use of these consumer apps should not be restricted. Baker agreed that the question was important. The EHR service authenticates the consumer. The authentication is not shared with the app. Leslie Kelly Hall said that the emphasis of the recommendation is on the provider's level of assurance. When apps are attached, the patient is responsible. Rishel agreed that the provider has no additional requirements when apps are involved. He was concerned about clarity so that no precedent was being set on requirements for apps. Baker said that the topic was a relevant one for registry services.

Arien Malec pointed out that the S&I Framework initiatives would be good pilot sites, calling out the data access initiative in particular. Additional funding for piloting and testing of FHIR may be required.

Halamka asked whether there were objections to transferring the recommendations to ONC with the addition of recommending pilot testing on the technologies. No objections were heard.

> **Action item #3: The above recommendations of the NwHIN Power Team on transport standards were accepted for submission to ONC without objection with the additional specification that pilot testing be undertaken and completed expeditiously.**

ONC Updates

Lauren Thompson, ONC, gave the S & I Framework status report. In terms of metrics, there are now 2,538 Wiki registrants and 746 committed members. The portfolio snapshot revealed that, among other initiatives, for the data segmentation for privacy initiative, pilots are in evaluation. Two implementation guides were adopted by HL7, and the RESTful implementation guide is still in the SDO adoption process. There was activity in longitudinal care and other areas as well. For more information, visit http://wiki.siframework.org/.

Mera Choi, ONC, said that a coordination of care workgroup was established. Mostashari asked for opinions about priorities. Malec said that priorities was too big and important a topic for a quick discussion. He referred to his previous experience in directing S&I projects. The number of projects should be kept small. If those affected know about the projects and do not participate, they have themselves to blame. But as an affected vendor, he declared that he does not have enough information to choose which projects to work on. With a smaller number of projects and more information about their expected end stage, better results could be expected. He suggested compiling a road map showing steps to the end stage. He noted that he was worried about the segmentation for privacy project because it lacked the engagement of implementers.

McCallie endorsed Malec's comments. In addition, he acknowledged that he was worried about HealtheDecisions. Data access is a good project on which to focus. He said that he likes BB+ pull.

Mostashari indicated that he was interested in suggestions for involving the committees in identifying priorities. The S & I participants represent a less diverse range of interests compared to the committees' memberships, often resulting in a mismatch between the participants and the members. People are interested in weighing in on an approach without taking the time to be involved. He asked for suggestions on a process. He emphasized that not everyone can be involved in every project. McCallie indicated that staff needs to find a way to convince vendors to be involved.

Kelly Hall commented that it is not always clear what problem a project is attempting to solve. Regarding segmentation for privacy, HIPAA does not give direction for filtering information. She expressed concern about the segmentation project. Halamka observed that the new regulations for which type of payment (self or third-party) must be taken in account are very difficult to implement.

Mostashari informed Kelly Hall that the HITSC does not need to weigh in on policy. She replied that overzealous standards may affect policy. Perlin acknowledged the interaction of policy and standards, saying that the two committees must cooperate and coordinate.

Rishel referred to the numerous checks and balances inherent in the advisory and regulatory processes. It is incumbent on the S&I leadership to have broad participation. Thompson emphasized that staff does outreach. Staff is working on a road map, which she offered to report on at the next meeting.

Jodi Daniel, ONC, announced that registration is open for the September 16 Consumer Health IT Summit: Accelerating the Blue Button Movement at: http://www.blsmeetings.net/2013HealthITSummit/index.cfm. HHS released a publication entitled *Strategy and Principles to Accelerate HIE*. It reflects stakeholder input received through a Request for Information.

CMS and ONC held a webinar August 7 to describe efforts to enable HIE across the entire health care system. Staff launched a new page on healthIT.gov to highlight HHS activities to accelerate HIE.

The healthIT.gov page also includes guidance to states on how to accelerate HIE through Medicaid programs and CMS and OIG rulemaking on extension of physician self-referral and anti-kickback rules governing donation of EHR software and services.

ONC released a progress report on the implementation of the Federal Health IT Strategic Plan 2011 – 2015. The report highlights resources and services the Federal government implemented to guide nationwide adoption and use of health IT. The report links to information on programs, reports, data, and other useful information on federal activities. The report is scheduled for updating in early 2014.

Daniel went on to describe a cross vendor exchange demonstration. ONC, CMS and NIST jointly released an approach to testing interoperability among Stage 2-certified EHR vendors, specifically to address the transition of care measure 3. Providers have two options under this measure. Most are expected to meet the measure by the first criterion by exchanging a summary of care record with another provider that has a different EHR. But under some circumstances, providers will meet this measure by the second criterion, which is exchanging with a CMS-designated test EHR. The demo addresses the second option. Documents were posted to explain how providers can use the testing infrastructure and participate in the program. The pilot with five-to-seven vendors will be launched in September in order to make it operational in alignment with the timeframe for EHs.

Daniel continued. As a follow-up to the report on HIT safety at the July HITSC meeting, ONC released the *EHR Contracts: Key Contract Terms for Users to Understand*. The guide is aimed at purchasers and users of EHR systems that are or may become legally bound by EHR technology developer contracts. It provides examples and plain language explanations that will assist purchasers and users of EHRs to understand and evaluate contract terms.

She mentioned HITPC activities. The Meaningful Use Workgroup was instructed to revise its draft recommendations for the September meeting. The FDASIA Workgroup presented preliminary recommendations in August. Several areas were identified as needing more work. Another report is expected at the September HITPC meeting. ONC, FDA, and FCC will use the FDASIA recommendations as input for a draft framework due January 2014. A comment period will follow. Comments specific to each agency are open and will close August 31. The Privacy and Security Tiger Team made a series of recommendations on security risk assessment, which were accepted, and recommended that no additional recommendation on non-targeted query was needed at this time. That recommendation was also accepted. The Information Exchange Workgroup is working on recommendations for data portability.

Malec asked for a complete report on the FDASIA recommendations. Daniel agreed to report at the next meeting. Halamka requested more detail on the privacy and security recommendations in order to determine the need for additional work on standards.

Public Comment

Consolazio announced the three-minute limit on comments.

Gary Dickenson, CentriHealth, Inc., commented that he had submitted a document describing his concern about the use and definition of interoperability, both the technical and semantic concerns. Use implies fitness for use. There are numerous limitations to fitness. His document includes a detailed analysis page.

Perlin asked staff to circulate information on the upcoming HIT week.

SUMMARY OF ACTION ITEMS:

Action item #1: A resolution in recognition of the leadership and public service of Farzad Mostashari was adopted unanimously.

Action item #2: The summary of the July 2013 HITSC meeting was approved with two minor corrections.

Action item #3: The above recommendations of the NwHIN Power Team on transport standards were accepted for submission to ONC without objection with the additional specification that pilot testing be undertaken and completed expeditiously.

Meeting Materials

Agenda
Summary of July 2013 meeting
Meeting presentation slides and reports