HIT Standards Committee
FINAL
Summary of the March 26, 2014 Virtual Meeting

ATTENDANCE

The following members attended the meeting:

Dixie Baker
Steve Brown
Anne Castro
Jeremy Delinsky
John Derr
Floyd Eisenberg
James Ferguson
Elizabeth Grippo for Keith Figlioli
Lisa Gallagher
John Halamka
Leslie Kelly Hall
C. Martin Harris
Stanley Huff
Elizabeth Johnson
Anne LeMaistre
Arien Malec
David McCallie, Jr.
Nancy Orvis
Jonathan Perlin
Wes Rishel
Kamie Roberts for Charles Romine
Eric Rose
Sharon Terry
Andrew Wiesenthal

The following members were absent:

Lorraine Doo
Rebecca Kush
Kim Nolen
Christopher Ross

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 55th 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. She called the roll and instructed members to identify themselves for the transcript before speaking.

Remarks

National Coordinator and Karen DeSalvo remarked that ONC is planning for Stage 3. She is looking forward to the in-person meeting in April.

Review of Agenda

Chairperson Jonathan Perlin asked for corrections of, additions to, or approval of the summary of the February meeting as circulated. He reported that Jamie Ferguson had requested in writing that the sentence "Jamie Ferguson said that many of the Continua specifications have yet to be considered by FDA" be changed to the effect that the standards have yet to consider FDA guidance. Hearing no additional requests for changes, Perlin declared the summary approved with the change requested by Ferguson. He noted the importance of each of the agenda items. The various workgroups will report on Stage 3 standards readiness at the April 24 meeting.

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

Comments

Vice Chairperson John Halamka referred to his recent work on Stage 2 compliance. He said that the Standards Task Force attempted to use the NwHIN Power Team's, chaired by Dixie Baker, criteria for standards readiness and total development effort in its review of the HITPC Stage 3 recommendations.

ONC Updates

Doug Fridsma provided slides on and mentioned the status of each of the projects in his portfolio. He showed the most recent stats on community participation. He described in detail the Clinical Quality Framework, saying that much of the standards harmonization work is already underway in HL7 work groups. It is expected to promote wider visibility into the standards under development and provide additional implementation-based feedback, leading to more robust specifications. The scope includes identification, definition, and harmonization of electronic standards that promote integration between CDS and eCQM in the areas of metadata, patient data model, and logical expression language. Regarding PDMP and HIT integration, staff is working with the Substance Abuse and Mental Health Services Administration (SAMHSA). They began the final review of the use case document, which focuses on how a health care professional using HIT can access a state PDMP to obtain prescription drug information for a patient. Relevant candidate standards analysis and outreach to SDOs and technical experts were initiated. Existing clinical standards will be mapped with PDMP.

Q&A

Halamka commented on the desirability of a unified workflow for the PDMP. David McCallie reported to Fridsma that FHIR may be a better solution and more forward-facing for Structured Data Capture and HealtheDecisions. He has so informed various persons on the workgroups. Jacob Reider, ONC, told McCallie to feel free to engage directly with the team, which is mapping VMR to FHIR.

Ferguson referred to efforts with the EU and the Trillion Bridge contract on methods for exchange of provider- and patient-mediated summaries. Fridsma said that all of the EU-US work is coordinated through the framework activities. The Trillion Bridge contract has time-sensitive deliverables that sometimes make coordination challenging. A Web mapping tool to move between one and the other will be released at the Athens meeting in May. The establishment of internationally recognized standards is desirable. Ferguson said that a Web service for bidirectional transmission could be a good solution. Fridsma asked that any additional comments or questions on the meeting materials be e-mailed to him.

2015 Edition NPRM

Steve Posnack, ONC, showed slides and reported that ONC has released the NPRM for the 2015 Edition. The proposed rule was published in the Federal Register in February. ONC will accept comments on the proposed rule through April 28, 2014. He invited comments. The final rule is expected to be issued in summer 2014. The proposed rule will allow for more flexibility and offer certification for BH and LTPAC EHRs. Incremental rule making is expected to enable keeping up with industry updates. Gap certification between the 2014 Edition and 2015 Edition and then between the 2014-2015 Editions and the 2017 Edition could significantly expedite certifications and reduce regulatory burden. It will also provide greater opportunity for public comment and earlier visibility into potential policy directions. He described a number of highlights of the 2015 Edition, such as a CPOE for lab order implementation guide (IG), an updated IG for lab test results, requirements for computable CDS, as well as interface requirements needed to request CDS guidance from a CDS supplier, and an implantable device list to record and display the unique device identifiers (UDIs) associated with a patient's implanted devices, syndromic surveillance, transmission of notifications, and other topics. ONC proposes to discontinue the concept of Complete EHR certification. Another proposal is to remove the existing regulatory burden that would require EHR technology designed for non-meaningful use (MU) purposes to include MU measure calculation capabilities in order to get certified and to permit "MU EHR Modules" and "non-MU EHR Modules" to be certified. The latter would not need to include the MU-specific measure calculation capabilities to get certified. He presented a list of topics under consideration for the 2017 Edition via ANPRM:

- Additional patient data collection
- Disability information
- US military service
- Work information industry and occupation
- Medication allergy coding
- Certification policy for EHR modules and privacy and security
- Provider directories
- Oral liquid medication dosing
- Medication history
- Blue Button +
- 2D barcoding
- Duplicate patient records
- Disaster preparedness
- Certification of other types of HIT and for specific types of settings
- Best way to distinguish beyond "EHR technology"
- Specific types of health care settings

Committee Discussion

Halamka reported that the Implementation Workgroup will prepare draft comments on the proposal. He suggested that members wait for the report to present their individual viewpoints. Nevertheless, many members commented. Wes Rishel said that although he heard the request to keep it short, he had general comments. The practical limits of certification should be recognized. Certification in the areas of interoperability and functional operation never represents a level of testing sufficient for assurance. Economic forces limit the time that can be spent in testing because that time must be reflected in the fees charged. Testing criteria themselves often have holes and must be revised in process. Posnack had acknowledged holes in the 2015 approach; there is a requirement that a 2015 product must accept a CCDA from either a 2014- or 2015-certified product. Rishel explained in considerable detail why that would be a fundamental problem and not work. Additionally, being certified and readiness for widespread

implementation are not the same. He continued and emphasized that there are testing procedures that are more rigorous than those currently associated with certification. HL7 is working on testing procedures. The industry must find ways of testing products. He referred to a conversation with Posnack and acknowledged that he had misread a portion of the NPRM, something that apparently would be less likely to occur if basic Web publishing standards were used in the NPRMs. He recommended that the government institute red lining with hot spots in its announcements, something that he understands is already underway.

Staff referred to the time allocated to the agenda item. Arien Malec acknowledged that several laudatory items and fixes to the 2014 Edition were included in the NPRM. He was concerned about timing: a three-year cycle may be too fast or too slow. Evidence of the capability to tolerate faster cycles should be collected. Signaling for 2017 may best be done through RFI-like approaches rather than NPRMs. He went on. The NPRM includes policy goals that were not reviewed by the HIT FACAs, such as the edge protocols for Direct for which no evidence of a desire for unbundling was presented. Evidence should be used in proposing policy.

McCallie endorsed Rishel's comments, adding something about factoring in technical changes within regulation cycles. Leslie Kelly Hall talked about the integration of the consumer in the ecosystem and the subsequent tension about readiness of standards. She suggested the concept of directionally appropriate for use with standards not yet ready for incorporation into regulation to signal without overburdening participants.

Andrew Wiesenthal was concerned about stages beyond monetary incentives: What will guide purchasers who want to know whether a product will meet their needs?

Dixie Baker expressed concern that the 2014 Edition did not require certification against basic, minimal privacy and security criteria as was recommended by the Privacy and Security Workgroup and approved by the HITSC. She assured Posnack that the workgroup will repeat its recommendations.

Posnack thanked the members for their comments. The NPRM includes another proposal for certification packages, a shorthand way to group criteria for a particular workflow or need, such as care coordination. Staff will use the discussion and public comments in the final rule. He told Baker that there is no need to repeat the recommendations; the NPRM will gather comments on those recommendations. As of December 31, 2013, 70 percent of EHR modules voluntarily certified for at least one privacy and security criterion and 51 percent for four or more. He urged the Privacy and Security Workgroup to focus on the implementation of its recommendations. ONC publishes a list of the areas in which products were certified.

Review of HITPC Meaningful Use Stage 3 Recommendations by the Standards Task Force

In his role of Task Force Chairperson, Halamka reported that in addition to task force members, assessments from several experts had been solicited and used to formulate comments on each of the 19 Stage 3 recommendations of the HITPC. He went through slides on each recommendation, describing the recommendation and certification criteria, and the rationale for the rating for provider use effort, standards maturity and development effort, the areas in which ONC staff had requested advice.

> Clinical decision support: provider use effort – high; standards maturity – low; and development effort – high. He paused for comments. McCallie announced his agreement.
>
> Order tracking: provider use effort – medium; standards maturity – low; and development effort – high. There were no comments from members.
>
> Demographics and other patient information: provider use effort – medium; standards maturity – low; and development effort – medium. Eric Rose said that implementation could have a punitive effect on vendors using emerging best practices and cause them to dumb down capture of information. Requirements should allow for more granular capture. Halamka reported that he had

reviewed the literature on standards for sexual orientation and gender identity and forwarded an important paper to ONC for distribution. Sex and gender identify are not easily categorized. A one-answer approach is not recommended.

Care planning and advance directive: provider use effort – low; standards maturity – high; and development effort – low. McCallie referred to nontrivial trust issues around URLs.

Electronic notes: provider use effort – medium; standards maturity – medium; and development effort – high. Halamka said that the lack of clarify regarding a search across all notes or within a note has yet to be resolved. Task Force members observed that the threshold was not reasonable. No comments were heard.

Hospital labs: provider use effort – low; standards maturity – high; and development effort – high. Regarding a concern with LOINC readiness and development, which he had agreed to investigate, Malec admitted that he had not done so. Baker pointed out that standards maturity is only one dimension of standards readiness. Rose noted the considerable work required to associate organism terms with SNOMED. Liz Johnson agreed. Halamka asked Consolazio to clarify the HITPC's intent regarding SNOMED.

Unique device identifiers: provider use effort – low; standards maturity – low; and development effort – low. Kelly Hall talked about UDI being useful to patients. Wiesenthal said that bar coding will soon be ready. SNOMED incorporates UDI. Rishel asked what is meant by validating UDI. Halamka replied that several validation methods are available; the nature of the validation method affects the development effort.

View, download, transmit: provider use effort – high; standards maturity – low; and development effort – medium. Ferguson described the burden of the time requirement as reported by a lab director. State law may require providers to discuss test results with patients prior to their release, which may constitute a burden for providers. He suggested addressing this concern in the standards by excluding such situations. Halamka acknowledged that some state laws may complicate workflows. Johnson called attention to the issue of minors.

Patient-generated health data: provider use effort – high; standards maturity – low; and development effort – high. McCallie advised an increased focus on outcome, and less on process. Kelly Hall described the use case as a non-tethered PHR. She favored giving good directional signals to promote patient adoption and integration. Stan Huff agreed with others about the need to question and clarify these recommendations. He wanted to focus on measuring outcomes and leave workflow to the discretion of implementers. He pointed out that most of these recommendations would have unintended consequences. They are too prescriptive and will stifle innovation. Halamka agreed that Huff's comment applies to secure messaging. Baker agreed with Huff.

Secure messaging: provider use effort – medium; standards maturity – low; and development effort – high. Members did not comment.

Visit summary and clinical summary: provider use effort – medium; standards maturity – low; and development effort – high. Halamka noted that this recommendation was particularly difficult to evaluate because of the multiple use of undefined terms. Steven Brown said that providers say the content of these summaries is not useful to their patients. Nancy Orvis said that she understood actionable to mean clear patient instructions or next steps.

Patient education: provider use effort – medium; standards maturity – medium; and development effort – medium-high. Kelly Hall said that Blue Button has the necessary capacity. Halamka emphasized that the HITPC must clarify the intent of the objective. Wiesenthal observed that the

ongoing work with the EU may help with solutions for preferred language. The EU is working on translations by native speakers.

Summary of care at transitions: provider use effort – high; standards maturity – medium, and development effort – medium high

Notifications: provider use effort – high; standards maturity – low; and development effort – high. Baker wondered about a requirement that measures must be implemented in certified EHRs. Halamka said that attestation can be achieved without certification. Baker suggested making an overall comment about the avoidance of over prescription.

Medication reconciliation: Halamka declared that there was nothing new to discuss.

Immunization history: provider use effort – medium; standards maturity – low; and development effort – high. Halamka acknowledge the extensive communications and comments that were generated by the recommendation. The transport mechanism is what is controversial. Malec informed the members that he was a member of the CDC committee that worked on the specifications. There is great variation across state immunization registries. SOAP was selected as being more valuable for a real-time query response to a registry. Rose commented on the terminology. Inbound data may not be accepted if the EHR does not have the latest CDX codes. Halamka said that although the content standard is mature, there is controversy regarding transport standards.

Registries: provider use effort – high; standards maturity – low; and development effort – high. Members made no comments.

Electronic lab reporting and syndromic surveillance have not changed from Stage 2.

The Standards Task Force also commented on the considerable, possibly overwhelming, overall effort required if the Stage 3 recommendations were implemented.

Public Comment

Alison Chi, American Immunization Registry Association, commented that her organization had submitted written comments, including an article about SOAP update.

Tom Bizzaro, First Data Bank, referred to the S&I Framework's workgroup on PDMP, saying that the workflow was indeed cumbersome. He recommended that additional work be undertaken.

Angel Apoate, NYC Department of Health and Mental Hygiene, said that SOAP web services were preferable to Direct. SOAP should be required for transport. Since only one implementation is required, the effort is low.

Kristen Forney, NYC Immunization Registry, reported that her department has been doing bidirectional exchange since 2009 with HL7. Only SOAP is used. Provider feedback is uniformly positive. Providers ask which EHR systems support this function and make their selections on that basis. Columbia Presbyterian was the first provider to establish bidirectional exchange with the NYC health agency. Analysis of Columbia Presbyterian immunization data found that in each age group immune coverage significantly improved with use of the registry. She recommended that insofar as Stage 3 is to focus on improved outcomes, the evidence supports the use of SOAP for the immunization registry.

The next meeting will be in-person April 24 in Washington, DC.

SUMMARY OF ACTION ITEMS:

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

Meeting Materials

Agenda
Summary of February 2014 meeting
Meeting presentation slides and reports
December meeting materials (draft workplan)
Comments and letters from interest groups