HIT Standards Committee
FINAL
Summary of the August 20, 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 (3-minute limit), and that a transcript will be posted on the ONC website. After calling the roll, she instructed members to identify themselves for the transcript before speaking.

Opening Remarks

Chairperson Jacob Reider, ONC, noted the maturity of the committee, whose mission goes beyond meaningful use and extends to HIT in general to balance rigidity and flexibility of standards. He asked for acceptance of the summary of the July meeting. Consolazio said that Dixie Baker had submitted an amendment to the summary distributed with the meeting materials. Co-chairperson John Halamka moved to accept the summary with Baker's addition and Andy Wisenthal seconded the motion. No objections to the motion were heard.

Action item #1: The summary of the July 2014 HITSC meeting was accepted.

Remarks and Review of Agenda

Halamka talked about the importance of interoperability, which goes beyond meaningful use, and its relationship to items on the agenda.

Workplan

Reider presented slides on the ONC FACA workplan through June 2015. This topic was added to the agenda after its distribution to members. The slides depicted the new FACA workgroup structure along with ONC activities. Staff responded to several questions. The JASON Task Force will present its recommendations for final action at the joint HITSC and HITPC meeting in October. The interoperability road map is not expected to state timeframes for certification. Although HITSC workgroups may be asked to comment on the strategic plan, primary responsibility for commenting rests with the HITPC. ONC will produce the revised strategic plan. Overlapping activities may or may not be timed for incorporation into current rule making. Although the FACAs' work is important, the rule making process is lengthy and coordination is difficult. Strategic thinking is underway.

Standards and Technology Update

Steve Posnack, ONC, showed slides and reported on the CMS-designated test EHR for stage 2 ToC measure 3. The designated test companies are: Medical Information Technology, Inc., iPatientCare, Inc., and McKesson, which is also Direct Trust accredited. He announced that McKesson will be retiring its

testing role in the near future. To date, 2,096 unique pairings to test EHRs by EPs and EHs, including EPs and EHs asking for a match with different designated test EHRs, have occurred. Approximately 58 developer products were matched, which does not necessarily mean that a test occurred. In December 2012, testing capabilities for new 2014 Edition Standards (CCDA and Direct) were generally unavailable. Current capabilities consist of: Direct, CCDA v1.1, QRDA I and III, provider directory; and a test platform available for pre- and post-certification testing. In FY 2015, the focus will be on interoperability with CCDA semantic interoperability testing based on a 3-year roadmap; SMART, etc.; Direct edge protocols; FHIR; and security (patient matching, authorization, consent management, and data segmentation). Posnack went on to describe the test environment targeting developers. There will be a validation suite for content and secure transport. Implementation issues will be tracked and responses to the knowledge base will be published. A discussion board will be moderated. The centralized set of tools consists of sandboxes for CCDA, QRDA, transport, and provider directory. The sample repository includes 53 sample CCDAs from 13 developers. More than 7600 CCDAs have been validated. His slides depicted the structure and use of the SITE. He concluded with an update on the status of and development timeframe for the active S&I Framework initiatives sponsors. Evolution of activities in three focus areas—public health, provenance, and lab services—were also described.

Q&A

In response to a question about resolution of disagreements on testing facilities or systems, Posnack indicated that disagreements can be raised via the SITE discussion board. Various experts and SDOs can be used for resolution.

Leslie Kelly Hall added numbers. This year Direct Trust memberships increased from 660 to 28,000; Direct addresses and accounts increased from 8000 to more than 425,000 and the number of messages reached 7,700,000.

David McCallie inquired about the degree of validation with CCDA and assurance that CCDA is working. Posnack responded that there is a SITE validator. There is a connection to regulation and an opportunity to reexamine certification criteria and to address more detailed testing. He said that he would welcome public-private sector work to enhance validation. Certification is one lever; there may be other testing approaches.

Halamka referred to slide 6 and the provider directory test bed, saying that according to criteria recommended by Dixie Baker's group (NwHIN Power Team), the cited standards are not the best. A robust approach to a directory is needed. Posnack indicated that he will get back to Halamka on that topic. A provider directory would solve many problems, according to Halamka.

Interoperability Updates

Erica Galvez, ONC, gave a slide presentation summarizing two definitions of interoperability, the ONC 10-year vision concept paper, and plans for a roadmap with five building blocks and nine guiding principles. The building blocks are: core technical standards and functions; certification to support adoption and optimization of IT products; privacy and security protections for health information; support business, cultural, clinical, and regulatory environments; and rules of engagement and governance. She announced that ONC committed to leading the development of a shared, national interoperability roadmap referenced in the 10-year plan concept paper. The roadmap will chart a course toward the vision. It will not be limited to federal government involvement. Its structure will be based on the vision, building blocks, and milestones described in the concept paper. She acknowledged tension among the nine guiding principles. The first version of the roadmap is expected March 2015. Some aspects of roadmap development are already underway, such as the JASON Task Force and the Governance Subgroup. ONC recently launched an online forum with a general solicitation for input on

priorities, use cases, and critical actions within each of the five building blocks. More details on the timeline and other aspects of the roadmap will be presented at the October meeting.

Q&A

Several members voiced approval of Galvez's plan. Wes Rishel referred to the slide with major deadlines and building blocks. Noting that the IEEE definition of interoperability leaves open how data are used, he asked whether 2020 is the earliest time to expect to be able to exchange structured data to drive decision-support algorithms and aggregate population data. Galvez indicated that results may possibly be seen before that time. She referred him to the concept paper for more details.

Eric Rose suggested adding a guiding principle about being mindful of potential ill effects of structured data. A lot of data is inaccurate and difficult to comprehend. Opening the floodgates to data aggregation can be scary. Regarding the building block entitled rules of engagement and governance, he wondered what it includes that is not in the other four building blocks. Galvez indicated that it could include implementation of aspects of other building blocks. An example would be user agreements.

Halamka spoke about the importance of setting realistic timelines that take into account cultural and other non-technological factors. McCallie observed that many roadmaps have been designed, but not all of them led to the intended destination: Did staff look at which worked and what was learned from past efforts? Galvez responded that staff is in the process of gathering that information. They are talking to folks in the field who have tried to advance interoperability. She invited members to submit descriptions of relevant experiences. McCallie predicted that the industry will move fast in the 6 years up to 2020 and may outstrip the roadmap. The challenge is to stay in sync.

Baker asked about the distinction between building on existing HIT infrastructure and taking the environment into consideration—both are listed as guiding principles. She suggested adding a principle on the need for stability and predictability since both technology and other aspects of the environment are continuingly evolving. Galvez agreed that the two principles are similar. A lot of clinical practices are not yet on board and should not be left behind. The broad ecosystem must be taken into account. Baker predicted that within the specified time period, most people will have electronic health care records.

Kelly Hall approved of the patient-centered definition of interoperability. Regarding leverage of the market, the consumer market should be considered. She said that demand can be a driver to advance the interoperability vision.

Wisenthal reported on legislation that would bind a number of children's hospitals so that individual patients with complex needs could access any one of them. He wondered whether ONC can act as a convener for organizations trying to promote accountable care. The national interoperability strategy should support such efforts. Galvez indicated that on-going coordination could be incorporated in the roadmap. She will follow up with Wisenthal offline regarding the legislation.

Rishel reflected that rather than looking for a sweet spot to balance rigidity and flexibility and for the market to evolve, one should think categorically and consider the maturity of use cases. Many EHR systems are offered in the market. Some vendors lead; others have to be dragged. Market timing is the way to deal with balance.

Data Review

Vaishali Patel, ONC, showed slides and summarized analyses of data from meaningful use reports, National Electronic Health Record Survey, NCHS Workflow Survey, AHA Health IT Supplement, ONC Survey of Clinical Laboratories, and reports by state HIE program grantees. She said that by Q4 2013, directed and query-based exchange was broadly available in 28 states and DC, meaning that a regional

or state exchange was in operation. Prior to stage 2 in 2013, physician exchange activity with outside providers was less than 14%. Hospital exchange activity grew significantly from 41% in 2008 to 62% in 2013. Exchange of data during transitions is limited for EHs and EPs, as evidenced by survey and early stage 2 data. The performance on summary of care and VDT is generally lower than performance of the other stage 2 core measures. In 2012, 5 in 10 physicians received discharge summaries routinely, but only 25% received them electronically. In 2013, 49% of hospitals reported they had the *capability* to send care summaries to an outside organization that used a different EHR. A significant number of individuals experience gaps in information sharing, although a significant portion of individuals who obtain access to their health information do view, download and share their data. About 1/3 of the US adult population reported experiencing at least one gap in the provision of health care information; persons with multiple chronic conditions are over-represented in this group. 28% of the adult population reported having online access to their personal health care information in 2013, but only 46% of them actually viewed the data, with fewer downloading or transmitting those data.

State HIE grantees report increased capabilities for query-based and directed exchange, as well as increased ability to support exchange through the provision of key services. Data show growth in exchange capability and activity, but also show substantial room for improvement.

She went on to say that although measures to date have focused on HIE rather than interoperability, staff is aligning measurement strategy to link directly to ONC's strategic vision. These efforts may include monitoring other types of information such as volume of transactions, adoption of standards, and availability of services that enable HIE.

Q&A

Referring to the map showing that directed and query-based exchange was broadly available in 28 states, McCallie characterized it as a patchwork: Some providers can exchange with some others, some of the time. No information is readily available on the extent of universal connectivity and exchange. He suggested that a measure be developed to capture universality. Galvez acknowledged that the map was limited to showing the availability of something to which to connect.

In response to a question about slide 11 and opinions on security measures and opinions, Galvez said that the survey item dealt with exchange with outside providers among respondents who had had experience with exchanges. There were no follow up items to obtain more explanation of responses.

Constraining the Consolidated-Clinical Document Architecture (CCDA)

Halamka announced that Reider had asked him to facilitate the discussion. The summary of care document has gone through many iterations. He told the members to, as they listened, keep in mind that ONC is in a writing regulations phase. The HITSC has an opportunity to influence the forthcoming NPRM. It can also give feedback when the NPRM is published. The work over the next 10 weeks is very important.

Implementation Workgroup Co-chairpersons Elizabeth Johnson and Cris Ross presented draft recommendations for the committee's action. The workgroup was charged to determine whether there are usability challenges with the CCDA v1.1 specification and associated implementation guidance (currently adopted in ONC's certification program) that hinder interoperability. And if there are challenges that hinder interoperability, to recommend how ONC can most effectively address these issues, including through future versions of the certification program. Invited testimonies from six users revealed problems with the transport of structured data due to vagueness in standards or testing processes and usability difficulties related to transferred data. Johnson reviewed slides prepared by staff

that summarized the problems, and suggested solutions, described in the invited testimonies. She emphasized the depth of the problems and the critical need to work on solutions.

The following draft recommendations were then presented:

- Near-term, practical action is needed that is not disruptive and helps improve interoperability using CCDAs
- More detailed and constrained specifications are needed that include clinical use cases to address common issues
- Conformance tools need to be published to optimize and validate real world instances of CCDA, establishing a site for public samples of CCDA documents, sections, and entries
- Evaluate standards and implementation guidance that separates clinically relevant narrative content from discrete information
- Recommend that ONC and the HITSC Steering Committee identify the appropriate mechanism to conduct a more in-depth review of CCDA challenges for improvement or potential replacement (e.g. FHIR). The Implementation Workgroup is supportive of collaborating with other FACA workgroups to form a joint group to conduct this review

Discussion

Halamka said that the motion (action requested) would be for the Steering Committee to identify mechanisms for a review, such as drawing on other experts. He indicated that the recommendations could be helpful outside of any NPRM. Johnson agreed.

McCallie wondered about the possibility of a process by which vendors could be rated on the capability of their products to generate CCDAs, such as a website to which a provider could send the results and have it formatted to an accepted standard. He reported that CommonWell found great variation in vendors' interpretations of what and how to include in a CCDA. Halamka spoke about the importance of taking the workflow into consideration. Posnack said that the SITE sandbox is available for both pre- and post-implementation testing and development and likely could be used for templates for forms and worksheets. There is a kind of scoring already involved.

Given the patient-centric definition of interoperability, Kelly Hall requested that the patient's role be taken into account.

Arien Malec endorsed the Implementation Workgroup's recommendations. He said that consideration must be given to allowing for sufficient time to use developing standards prior to their certification. On another point, he observed that the CCDA tries to conflate machine-to-machine readable data with human readable narratives. Someone needs to examine approaches that would separate the two functions. Templates that compile and provide all available data are not particularly useful to clinicians. The structured data and the clinical narrative are different products. McCallie said that FHIR has the potential for use for both discrete data and a list of documents that can be fetched for narratives. Floyd Eisenberg reiterated the point about structured data and narratives, saying that the secondary use of data for CDS should also be addressed. Rishel reminded the members of the directive to think beyond meaningful use. People would like to build outside of the infrastructure because they have existing code in that EHR. In many situations in which the CCDA creates an individual file format specification or document specification, it becomes a wire protocol when it combines with another protocol. There are projects forecasting data from EHRs into a format that can be built as a report in a clinical trial. Although there is enthusiasm for FIHR as a possible alternative to CCDA, its value has yet to be tested extensively. People need help to determine whether to wait for FHIR or adapt the CCDA. What is the cost of the latter? Halamka said that they need a 6 to 8 month road map for an iterative process to get there.

Nancy Orvis referred to agency and congressional inquiries into the CCDA and its implementation. ONC should spend time with different interests to work something out. Implementation guides and use cases should be considered.

Halamka placed a motion on the table that an appropriate workgroup be assembled to continue the work of the Implementation Workgroup—to evaluate the CCDA, tools, artifacts and guides etc. He asked about objections and, hearing none, declared the motion approved. Reider said that the HITSC Steering Committee would designate the structure for carrying out the recommendations and make assignments. Given the general concern about the proliferation of workgroups, an existing workgroup or a subgroup will likely be assigned the work.

> **Action item #2: The recommendations of the Implementation Workgroup for constraining the CCDA were approved.**

The HITSC is scheduled to meet virtually September 10. An in-person joint meeting with the HITPC is scheduled for October 15.

Public Comment

None

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the July 2014 HITSC meeting was accepted.

Action item #2: The recommendations of the Implementation Workgroup for constraining the CCDA were approved.

Meeting Materials:

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

Meeting Attendance								
Name	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14	02/18/14	12/18/13
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
Jacob Reider	X	X	X	X				
James Ferguson	X	X	X	X	X	X		X
Jeremy Delinsky					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
Keith J.				X		X		

Figlioli								
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	X
Stanley M. Huff	X	X	X	X	X	X	X	X
Steve Brown				X	X	X	X	X
Wes Rishel	X	X	X	X	X	X	X	X
Total Attendees	**20**	**22**	**24**	**21**	**23**	**24**	**23**	**21**