HIT Standards Committee
FINAL
Summary of the September 22, 2015, Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator for Health Information Technology (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 Act meeting with an opportunity for public comment (3-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.

Opening Remarks

Deputy National Coordinator and Chairperson P. Jon White introduced new members: Jitin Asnaani, CommonWell Health Alliance, representing health exchange; Patricia Sengstack, Bon Secours Health System, Inc., representing providers; Josh Mandel, Children's Hospital Boston, representing providers; Richard Elmore, Allscripts Healthcare Solutions, Inc., representing vendors; and Angela Kennedy, Louisiana Tech University, representing consumers. They will be installed as voting members in October. Until that time, the retiring members, who are familiar with the topics being deliberated, will continue to participate.

Review of Agenda

Vice Chairperson John Halamka said that terms of five additional current members will soon expire, and their replacements will be announced at upcoming meetings. Halamka asked whether there were corrections or additions to the summary of the August 2015 meeting, which was circulated with the meeting materials. Hearing none, he declared the summary approved.

Action Item #1: The summary of the August 2015 meeting was accepted.

Halamka observed that the recommendations to be presented were based on the previously approved work of the NwHIN Power Team, chaired by Dixie Baker, on standards readiness. The purpose of the HITSC discussion was to determine whether the recommendations were valid given the previously adopted criteria for readiness. He declared that meaningful use stages 2 and 3 and the deputy national coordinator position would not be discussed. He said that although he had sought answers to questions on those topics, ONC cannot provide answers. The next 18 months will bring appropriate standards to enhance interoperability to keep Congress and stakeholders happy as the industry moves from fee-for-service medicine.

White added that the HHS HIT Strategic Plan was released September 21. He announced the October 9 departure of Jodi Daniels, ONC, and thanked her for her contributions.

Precision Medicine Task Force Recommendations

Task Force Chairperson White reported that the task force was charged as follow:

- Identify opportunities for innovative collaboration around pilots and testing of standards that support HIT interoperability for precision medicine

- Recommend existing standards that are currently ready to support the Precision Medicine Initiative (PMI)
- Identify emerging standards and reference implementations that may require further pilot testing in order to support PMI
- Identify gaps in available data standards related to PMI

Task Force Co-chairperson Leslie Kelly Hall explained that recommendations were made (and shown on slides) in four color-coded categories:

- Readily applicable standards for PMI (green) that can be put to use to support the PMI cohorts
- Promising standards for PMI (yellow) that may require additional effort to bring to use
- Standards gaps for PMI (red) where considerable work is needed
- Accelerators (blue), which are opportunities to advance and improve standards

The task force also indicated the actions to advance the designated standards: (a) form a task force to advance, (b) apply accelerators, or (c) follow existing standards process. Kelly Hall went through each of the recommendations slides and explained the rationales.

The following recommendations were presented on readily available standards (green):

- Precision medicine efforts should align to standards currently referenced in the 2015 Interoperability Standards Advisory (ISA), where they are included in current regulation, including the EHR Incentive Program and HIT Certification Rules (e.g., race and ethnicity, family health history and clinical genomics, gender identity, sex and sexual orientation, patient preference and consent).
- Use standards to capture and represent family health history such as SNOMED CT and the HL7 family health. history and pedigree model for familial relationships in order to express as a pre- or post-coordinated code
- Leverage the HL7 Clinical Genomics Work Group suite of standards (e.g., CDA, FHIR, v2, domain analysis model).

Promising standards (yellow) recommendations were as follows:

- FHIR could be included as an emerging standard, especially for transport of data. Argonaut may provide opportunities to advance. Sample uses of FHIR include authorization, genetics, family health history, and building on current work on SMART and FHIR Genomics.
- Open ID Connect, OAuth, and UMA should be considered for single sign-on. Further piloting and testing should be considered.
- Computable patient consent standards exist but lack adequate implementation guidance. (A lower priority will be handled separately from the standards process.)
- Include more complete authorization standards (e.g., IHE XUA, IUA). Ensure that authorization standards are compatible across disparate networks.

A slide with the following gaps (red) recommendations was presented:

- ONC should convene a stakeholder group to address computable patient consent. Standards exist, but without clear implementation guidance.
- Regarding race and ethnicity, OMB standards may be suitable for some purposes but inadequate for precision medicine and directing therapy or clinical decisions.
- ONC should work with stakeholders to define the minimum dataset and/or the means required to make precision medicine data useful in an EHR and in a clinical setting.
- Establish microbiome data standards.
- Capture of sexual orientation and gender identity remains challenging. ONC should consider recent efforts of the Fenway Institute in this area.

Accelerator recommendations (blue) were the following:

- 2016 PMI S&I: additional ONC investment in pilots of FHIR for PMI research and individual data donation use cases
- Incorporation of HPO in the UMLS Metathesaurus and connections between HPO and SNOMED CT
- OMIM: codes for phenotypes, genotypes, and links between the two

- dpSNP and ClinVar: an opportunity to develop a service that would consume data from these sources and synthesize so that it is digestible for a clinical information system

White noted that in the event of any future guidance, those standards would be added.

Discussion

Halamka directed attention to the green slide and asked whether the standards listed merited the readily applicable designation. David McCallie, a member of the Precision Medicine Task Force, disclosed that he had missed the meeting when the recommendations were finalized. He said that his only concern was with the recommendation to leverage the HL7 Clinical Genomics Work Group suite of standards, because some of that content is not relevant to PMI. Many of those standards are focused on behind the scene genomic issues that are probably better dealt with by the Global Alliance for Health. More robust biomarker models than are currently accounted for in the common use of the HL7 reference are needed. The models that are starting with FHIR are the ones that will capture the most attention in the coming years.

Steve Brown referred to family history and the HL7 standard versus SNOMED CT or some combination thereof. This is an opportunity to do post-coordination to enhance content coverage. What did the task force think about post-coordination using SNOMED CT family relationships or some other approach in a post-coordinated fashion with SNOMED CT? If that is the recommendation, what about the overlap between family relationships involving the same close coordination? It is complicated. White responded that the task force members recognize that more discussion is needed. Regarding actions, the task force recommended applying accelerators, which means to coordinate existing resources. Someone will have to figure out how to make it all come together. White apologized to McCallie, saying that there was not time to obtain approval of the recommendations from task force members. McCallie requested to amend the recommendations by moving IOM Genomics Roundtable from yellow to green. White and Kelly Hall agreed.

Baker agreed with McCallie about the HL7 genomics work. She suggested changing the HL7 Clinical Genomics suite of standards from green to yellow and recommended that ONC support the work of that work group. She went on to suggest that White and Kelly Hall look at the HL7 draft from the IOM digitized action collaboration. Some of that work would merit a green designation. Halamka observed that there was consensus that the last bullet on the green slide was more yellowish than greenish.

Anne LeMaistre asked whether the task force had discussed security for transmission and storage of data. Kelly Hall responded that task force members understood that these data require a greater sense of responsibility, because they define who one is. Identity management may be considered separately. The task force declined to make specific recommendations because additional work is being done by other groups. White pointed out that cohort members are participants, not research subjects. Security is a very important focus for PMI. ONC's role is to advance standards in conjunction with OCR and other agencies. LeMaistre noted confusion in the market, saying that anything that ONC can do to clarify for the market would be appreciated.

Halamka summarized that the last bullet on the green slide will be divided, with one part going to yellow. He directed attention to the yellow slide. Baker said that the task force should engage with the Global Alliance group working on regulations and ethics. McCallie pointed out that in reference to building a cohort, the NIH PMI group referred to a different consent model and changes to the Common Rule. Many parts are moving. He suggested that the difference between consent for care and consent for research be clarified and that the new ways of considering them be described. Baker agreed. It is widely recognized that genomic data are identifiable, and consent should be granular, but to what extent and by what process are up for discussion. White said that various NIH PMI groups are working on these issues, which are related to the JASON Report. McCallie suggested changing the recommendations to indicate to which ones HIPAA and the Common Rule respectively apply. Someone reported that the comment period for the Common Rule NPRM is in effect.

Halamka pointed out that computable patient consent is listed on both the yellow slide and the red slide. White declared that it could be deleted from the red slide. Baker suggested making it orange. Kelly Hall said that computable patient consent can be constrained for this cohort. They agreed to constrain it and delete it from the red slide.

Halamka called for discussion of the red (gaps) slide. He stated his support of the Fenway Institute's system of classification. Baker pointed out that sexual orientation and gender identity appear on both the green slide and the red

slide. Halamka suggested striking sexual orientation from the green slide. Kelly Hall explained that gaps and overlaps exist. White suggested deleting "(e.g., race and ethnicity, family health history/clinical genomics, gender identity, sex and sexual orientation, and patient preference/consent)." Halamka, Baker, and Kelly Hall agreed.

Members had no comments, questions, or suggestions on the accelerators slide. Halamka said that with the few changes being made, the recommendations are acceptable. He asked whether anyone disagreed with accepting the recommendations. Consolazio said that a formal vote was not required. Hearing no objections, Halamka ruled that the recommendations were approved as amended.

> **Action item #2: The recommendations of the Precision Medicine Work Group were accepted with a few minor changes**.

ISA Update

Steve Posnack, ONC, reminded the members that the ISA is a nonregulatory, straightforward approach with an interactive, predictable process for updates. It reflects the best available standards and implementation specifications as of the end of the calendar year. The intention is to provide a single, public list of the standards and implementation specifications to fulfill specific clinical health information technology interoperability needs. It reflects the results of ongoing dialogue, debate, and consensus. Also, it documents known limitations, preconditions, and dependencies among referenced standards and implementation specifications. Posnack reviewed the ISA process; the current step is the ONC review of the HITSC recommendations and the public comments on those recommendations. ONC staff will then prepare the next year's ISA for publication. Posnack described the major restructuring of the ISA as a result of recommendations. Purpose was changed to interoperability need. Staff added an emerging row to the table for standards and implementation specifications. They removed the transport section and inserted an appendix that contains sources for security standards. Finally, they added the following six informative characteristics for each standard and implementation specification:

- Standards process maturity (final, draft)
- Implementation maturity (production, pilot)
- Adoption Level (scale 1–5)
- Regulated (yes, no)
- Cost (yes, no)
- Test tools (yes, no)

Posnack showed and explained examples of changes in the tables. He said that in terms of other HITSC task force recommendations principles are being built into new processes and were adopted incrementally into operations. Recommendations to convene groups to address specific sections and standards are being considered but have not yet been addressed. Several additions and changes to standards and implementation guides were made. Other recommendations are being considered. The ISA draft for comment, released September 22, (https://www.healthit.gov/standards-advisory/2016) is open for public comment through November 6, 2015.

Q&A

Eric Rose asked what it means for a standard or implementation guide to be regulated. Posnack replied that a description of each characteristic is given in the ISA. The easiest way to designate "yes" is when the standard is included in ONC certification regulation. Alternatively, a "yes" could indicate areas in which particular standards are named for regulation by other agencies.

Baker said that she very much appreciates the use of the NwHIN Power Team's work on standards readiness, which was later documented in a journal article. She said that credit was also due to team members McCallie, Cris Ross, Wes Rishel**,** Jitin Asnaani, Arien Malec**,** and others. Nancy Orvis commended the work to clarify the ISA.

Rishel commended the contributions due to Baker's leadership. He inquired about the bubbles used to indicate level of adoption. He said that he is specifically sensitive to the ambiguity in terms of how the interoperability needs are met by a standard. For example, earlier versions of the CDA-derived documents were often described as supporting both a text representation and the ability to carry structured detailed information and data. To the extent that recipients used the CDAs, they were used solely for display. He urged evaluation of the high bubbles in terms of the actual value received for

interoperability. Posnack acknowledged that little is known about the extent to which the standards are used. Halamka pointed out that the public can comment on the bubbles, and staff can make changes as necessary. Although the bubbles are not based on empirical evidence, Posnack said that their use will stimulate conversation. Rishel observed that in his experience public comments to government drafts are usually polite, but are not sufficiently specific to be helpful. He suggested that ONC build information gathering processes into the next year's advisory.

Closure

The October, in-person meeting will be held jointly with the HITPC. White thanked everyone.

Public Comment

Donna Doneski wrote the following:

> *The National Association for the Support of Long Term Care (NASL), whose members include health IT developers/vendors and providers of care for the long term and post-acute care (LTPAC) sectors, appreciates the work of the Health IT Standards Committee. Our members are actively working on the exchange of health information for their clients, to include electronic exchange of health information across care. We will look forward to reviewing the 2016 Interoperability Standards Advisory and to offering comments. Thank you.*

SUMMARY OF ACTION ITEMS:

Action Item #1: The summary of the August 2015 meeting was accepted as circulated.

Action item #2: The recommendations of the Precision Medicine Work Group were accepted with a few minor changes.

Meeting Materials:

- Agenda
- Summary of August 2015 meeting
- Meeting presentation slides and reports

Meeting Attendance

Name	09/22/15	08/26/15	06/24/15	05/20/15	04/22/15	03/18/15	01/27/15	12/10/14
Andrew Wiesenthal	X	X		X	X	X	X	X
Angela Kennedy	X							
Anne Castro			X	X		X	X	X
Anne LeMaistre	X	X	X	X	X	X	X	X
Arien Malec		X	X	X	X	X	X	X
Charles H. Romine				X	X	X	X	
Christopher Ross			X	X	X	X	X	
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson	X		X		X	X	X	X
Eric Rose	X	X		X	X	X	X	X
Floyd Eisenberg	X	X	X	X		X	X	X
James Ferguson	X	X		X	X	X	X	X

Jitin Asnaani	X							
John Halamka	X	X	X	X	X	X	X	X
John F. Derr	X		X		X	X	X	X
Jon White	X	X	X	X	X	X	X	X
Josh Mandel	X							
Keith J. Figlioli		X	X	X		X		X
Kim Nolen	X	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	X
Lorraine Doo	X		X		X	X	X	X
Nancy J. Orvis	X		X		X	X	X	
Patricia P. Sengstack	X							
Rebecca D. Kush	X	X		X			X	
Richard Elmore	X							
Steve Brown	X		X		X			X
Wes Rishel	X		X	X	X	X	X	X