HIT Standards Committee
DRAFT
Summary of the December 10, 2015, Virtual Meeting

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 HITSC Chairperson P. Jon White thanked the members. He reminded them that Vice Chairperson John Halamka will rotate off the committee in January. ONC officials have selected new co-chairs: Lisa Gallagher and Arien Malec. This represents a significant change from the current structure, in which the ONC deputy national coordinator serves as chairperson. Henceforth, the deputy national coordinator will serve as an ex officio member.

Review of Agenda

Halamka congratulated Gallagher and Malec on their appointments. He mentioned the importance of each agenda item. He noted that recent press reports stated that, according to ONC staff, interoperability will be complete in 2016. However, those reports constitute misstatements or misinterpretations. What ONC staff actually said was that certain use cases and transactions, such as notices of admissions, are more or less ready for interoperability. White added that substantial progress is expected is 2016. Material will soon be published to clarify the statement on interoperability. Halamka asked whether there were corrections or additions to the summary of the November 3, 2015, meeting. The summary was circulated with the meeting materials. Hearing none, he declared the summary adopted.

Action Item #1: The summary of the November 2015 meeting was adopted as distributed.

Malec commented that interoperability is getting more attention. As a co-chair, he wants the HITSC to have a clear and renewed sense of purpose. He thanked the ONC staff. Gallagher said that she was honored and humbled to accept a co-chairpersonship. She looks forward to working with the members.

Certified Technology Comparison Task Force Update

Task Force Co-Chairperson Cris Ross reported that the work of the task force is based in the Medicare Access and CHIP Reauthorization ACT (MACRA), which calls for a study and report to Congress on the

feasibility of a mechanism(s) to assist providers in comparing certified HIT products. The task force is charged with making recommendations on the benefits of, and resources needed to develop and maintain, a certified HIT comparison tool. The task force was told to identify the different HIT needs for providers across the adoption and implementation spectrum, with particular focus on providers with limited resources and/or lower adoption rates; identify user needs for a comparison tool; and identify gaps in the current tool marketplace, and the barriers to addressing those gaps. Two virtual hearings are planned for January. Final recommendations will be submitted for action to the HITSC and HITPC on January 20, 2016. Five panels will be convened for the hearings, with each panel comprising a specific type of developer or user of certified products—primary care providers, specialists, certified HIT developers, HIT comparison and information tool vendors, and persons with expertise in quality improvement and advanced payment model capabilities.

Task force members had drafted a set of questions for each panel, and the questions were listed on the presentation slides. Ross and Task Force Co-Chairperson Anita Somplasky asked members to review the questions and submit any comments to staff.

Discussion

Regarding the composition of the panels, Jamie Ferguson said that multi-specialist practices should be represented. Malec wondered about hospitals and LTPAC providers that may be consumers of these tools. Consolazio interjected that a LTPAC representative has been invited to participate in a panel.

Eric Rose objected to limiting the third panel to certified vendors. Ross reminded him that certified EHR vendors are specifically called out in the language of MACRA. Rose went on to say that consumers of products are currently prohibited in their agreements with vendors from sharing information about their systems. Sharing screen shots with other users would be very helpful, and ONC should consider use of this policy lever.

Dixie Baker acknowledged that the task is a huge one. Providers are increasingly being pressured to make data available to secondary users. She recommended that the task force look at that burden. Andy Wiesenthal recommended that questions to panelists be constructed to differentiate between concerns with continuing to work as in the past and learning new ways to improve care. Noting that more than functionality is considered in purchasing products, Rich Elmore inquired about the scope of the forthcoming recommendations. Ross responded that the task force has talked about cost, usability, characteristics of vendors, and the experiences of regional education centers. Patricia Sengstack wondered about an interim report or draft subsequent to the submission of recommendations in January. She was interested in the inclusion of cost and other factors. Ross said that any interim report and feedback will be up to ONC. Dawn Heisey-Grove, ONC, referred to the April deadline for the report to Congress and indicated that following the committees' action in January, a report will be finalized by staff and sent through clearance. There will not be time for additional reviews and feedback by the public. Ross agreed to take the members' comments into consideration. He declared that the task force will cast a wide net, taking into account the time constraints.

Returning to the topic of the panels, Sengstack asked which panel might include a nurse informaticist. Ross said that such a clinician would be appropriate for panel I or II; he requested nominations. Consolazio interjected that a nurse informaticist is on the list of invitees.

Transitional Vocabulary Task Force Recommendations

Transitional Vocabulary Task Force Co-Chairperson Christopher Chute showed slides and explained that the task force was charged with this question: Should transitional vocabularies be eliminated as alternatives in reporting to federal quality measure programs using EHR-captured clinical data

elements? If so, which ones and by when? After their discussions and collection of information, the task force members agreed on recommendations. Transitional Vocabulary Task Force Co-Chairperson Floyd Eisenberg presented the following recommendations:

- We support the original intention of the HITSC to migrate towards encoding data to primarily support evidence-based patient care, clinical decision support, and clinical workflow rather than administrative activities.
- We also believe this coding will better support a broad array of functions, including evidence-based clinical care, clinical decision support, clinical workflows, quality measurement, research and reimbursement.
- The federal government should choose a date in the future to transition to clinically focused data capture and away from the support of multiple code systems for a single type of data. Thus, the task force ultimately supports one mandated reporting and exchange vocabulary for each category of data.
- Even after migration to a single terminology for clinical data, "hybrid measures" could still continue to intentionally incorporate and combine clinical and administrative terminologies (e.g., EHR data and claims reports). The use of administrative data, where specified, should be deliberate.
- It will be acceptable to use federally permitted deconstructions of other codes into SNOMED expressions. A deconstruction is defined as the representation of a complex, pre-coordinated expression with a set of simple coded statements such that when the set is interpreted as a post-coordinated expression the set renders the same meaning. The use of intentional value sets should be encouraged, i.e., where the members of the set are self-defining under the SNOMED hierarchies and relationship models. The use of post-coordinated SNOMED expressions should be encouraged for secondary use cases but not for primary data capture. A SNOMED expression library could, in the future, support exchange of complex ideas with a single identifier (i.e., pre-coordinated expressions), but such a technical solution is not yet available in exchange standards. The CPT and ICD-11 models may also support this approach coordinated with SNOMED in the future.
- Transitional or alternative vocabularies will continue to be used for reporting and exchange until single, data-specific terminologies are identified and incorporated into standards and programs.

Discussion

Malec asked to whom the recommendations are directed; who would be doing what in their implementation? Chute replied that in its coordinating role ONC should assemble the appropriate partners to agree on processes. The recommendations are deliberately vague in that regard.

Ferguson supported the recommendations. He pointed out that the National Library of Medicine is the publisher and national release center for SNOMED and ICD-10 and cross-mapping resources. Chute said that the recommendations go beyond mapping to aggregation and clustering of diagnostic categories. Simple code-to-code mappings do not yet do that. Ferguson responded that, since relatively complete code system mappings are currently available, these systems could begin to be used in transitions now. Eisenberg noted that the task force discussed, but declined to recommend, time lines. Considerable time will be required, possibly 10 years. Chute said that clinicians should not be burdened further with more structured data and granular coding.

Wes Rishel noted the difference between categorization and a bottom-up structure such as SNOMED. The recommendations are based on a vision of pre-coordinating administrative codes: Is there proof of feasibility? Will this meet the needs of payers? Halamka pointed out that certain organizations have

translational vocabularies as profit centers: What will be the effect of the recommendations on those organizations? Will there be a smooth trajectory? Chute indicated that the task force was not charged with designing a change strategy. Although Anne LeMaistre endorsed the recommendations, she too expressed concern about the absence of a change management strategy.

Eric Rose talked about SNOMED and granularity, saying that SNOMED runs the gamut from low to high granularity. The problem is how to handle the one-to-many translations. Chute talked about phenotyping and aggregation logic, which is done by machines. Regarding feasibility, he referred to developers' prototypes that are not yet ready for prime time. Rose used the example of excising a mole to argue that much would have to be worked out. Eisenberg said that using decision support a physician can access CPT auto code.

Rishel raised the issue of what data are collected for payment versus what data are collected for patient treatment. To make the recommendations work, someone in authority would have to show payers that the approach is feasible. Work must be done to convince that authority.

Ferguson pointed out that tens of thousands of physicians capture 98% of these data using SNOMED applications. Research can be done on how they do it, and how they deal with exceptions. Although algorithmic aggregation is the goal, the time line should be accelerated by using mapping.

Rishel asked for a citation for the 98% figure. Halamka said that the comments support the recommendations without the need for material revisions. Eisenberg noted that since the task force did not recommend the next step, the point made during discussion that ONC should use its convening function to go forward should be added to the recommendations. No objections were heard. Halamka declared the recommendations accepted.

> **Action item #2: The recommendations of the Transitional Vocabulary Task Force were accepted for forwarding to ONC with the addition that ONC use its convening authority to gather potential partners to plan for implementation.**

Precision Medicine Task Force Update

In his role as Precision Medicine Task Force co-chairperson, White repeated the explanation of ONC's assigned role in the precision medicine initiative (PMI) that has been presented at previous meetings. The PMI is advancing in NIH and ONC. At the September 22, 2015 meeting, the HITSC approved the recommendations submitted by the task force. The final recommendations were organized in four categories and shown on slides: readily applicable standards, promising standards, standards gaps, and accelerators. White said that these recommendations complement recommendations from the NIH advisory groups.

White announced that the task force will be reconvened to consider the following questions:

- How can ONC support the use of emerging standards (FHIR, OAuth 2) to support individual data donation to PMI?
- What is the best way to execute the recommendation that ONC convene stakeholders to address dynamic computable consent?
- What existing work can ONC support to improve race and ethnicity standards and capture of sexual orientation and gender identity data so that they are adequate for precision medicine and directing therapy or clinical decisions?
- How should ONC execute on the recommendation to define the minimum data set and/or means required to make precision medicine data useful in a clinical setting?

White said that although he will serve as an ex officio member, Wiesenthal and Leslie Kelly Hall will co-chair the task force. He invited the other task force members to continue their participation.

Discussion

Halamka reported that the Fenway Community Health Center has clinically validated a set of questions and responses to use in place of gender identification coding. The responses provide information to clinicians to use in providing care. White agreed to seek more information on that topic.

Although the task force recommendations were approved at a previous meeting, Baker described several errors. Referring to slide 5 (readily applicable standards), she said that DIGITizE has moved on to the next specification; the slide should be updated. The reference to Open ID Connect, OAuth and UMA on slide 6 should be restated to support OAuth 2 and its profiles. Baker went on to object to the phrase "include more complete authorization standards," wondering what is more complete. Regarding slide 7, she observed that the statement about existing standards was not clear. Furthermore, the line "microbiome, exposome, etc. data standards" is not a recommendation. Baker continued. In general, genomic standards are evolving globally. The recommendation should be to follow and facilitate international standards for genomic data. White indicated receipt of the comments.

Malec commented on the common rule, HIPAA, and computable consent. Harmonization and guidance would be helpful when HIPAA and the common rule are applicable. Regarding computable consent, the focus is on the patient and legal agreement. However, if one considers purpose of use, a more substantive answer may be obtained. Better regulation of purpose of use would be helpful. When data donation is the purpose, the path is clear. Precision of purpose of use is desirable. The Argonaut Project work is applicable to data donation. One system can request data on individuals from another system, but the industry has not made progress in requesting population level queries. Purpose of use and authorization of use will allow multiple uses of data.

Baker added that she agreed with Malec on computable consent and purpose. Consent must be dynamic so that individuals can make changes in the use of their data. Ferguson commented on purpose of use: One PMI scenario is submission of data to registries, and he agreed with that recommendation; but PMI is proposing something entirely different, and it involves issues that must be carefully considered.

Closing Remarks

This item was added to the agenda that was distributed in advance of the meeting. White thanked everyone again, saying that 2015 was quite a year. He mentioned a few of the many projects: the HHS HIT Strategic Plan, the Interoperability Roadmap, MACRA, new rules, and ICD-10 implementation. Standards play a critical role in each of these efforts. Many task forces, workgroups, and committee meetings and reviews occurred. Several ONC personnel transitions took place. White thanked the outstanding staff members who support the HITSC. He referred to the honor of working with Halamka. Halamka made additional remarks, saying that, all in all and looking at the trajectory of this last year, much progress was made. The new co-chairs and the committee can act as a board of directors and drive the ONC agenda.

Public Comment

None

SUMMARY OF ACTION ITEMS:

Action Item #1: The summary of the November 2015 meeting was accepted as distributed.

Action item #2: The recommendations of the Transitional Vocabulary Task Force were accepted for forwarding to ONC, with the addition that ONC use its convening authority to gather potential partners to plan for implementation.

Meeting Materials:

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

MEETING ATTENDANCE

Name	12/10/15	11/03/15	09/22/15	08/26/15	06/24/15	05/20/15	04/22/15
Andrew Wiesenthal	X	X	X	X		X	X
Angela Kennedy	X	X	X				
Anne Castro		X			X	X	
Anne LeMaistre	X	X	X	X	X	X	X
Arien Malec	X	X		X	X	X	X
Charles H. Romine	X	X				X	X
Christopher Ross	X				X	X	X
Dixie B. Baker	X	X	X	X	X	X	X
Elizabeth Johnson			X		X		X
Eric Rose	X	X	X	X		X	X
Floyd Eisenberg	X	X	X	X	X	X	
James Ferguson	X		X	X		X	X
Jitin Asnaani	X		X				
John Halamka	X	X	X	X	X	X	X
John F. Derr	X	X	X		X		X
Jon White	X	X	X	X	X	X	X
Josh Mandel		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
Lisa Gallagher	X		X	X	X	X	X
Lorraine Doo	X	X	X		X		X

Name	12/10/15	11/03/15	09/22/15	08/26/15	06/24/15	05/20/15	04/22/15
Nancy J. Orvis	X	X	X		X		X
Patricia P. Sengstack	X	X	X				
Rebecca D. Kush			X	X		X	
Richard Elmore	X	X	X				
Steve Brown			X		X		X
Wes Rishel	X	X	X		X	X	X