Health Information Technology Advisory Committee

U.S. Core Data for Interoperability Task Force 2021 Virtual Meeting

Meeting Notes | April 13, 2021, 10:30 a.m. – 12:00 p.m. ET

Executive Summary

The focus of the U.S. Core Data for Interoperability Task Force 2021 (USCDI TF 2021) meeting was to complete a final review of Phase 1 of its work, which will culminate in a presentation by the co-chairs of the TF's recommendations to the HITAC on April 15, 2021. Copies of the recommendations were sent to TF members. The TF discussed its next steps, summer meeting schedule, and plans for Phase 2 and Phase 3 of its work. Recommendations from Phases 2 and 3 are due to the HITAC by September 9, 2021.

There was one public comment submitted by phone, and there was a robust discussion in the chat feature in Adobe Connect.

Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Past Meeting Notes
10:40 a.m.	Review Phase 1 Work
11:10 a.m.	Review TF Recommendations to HITAC
11:20 a.m.	TF Schedule/Next Meeting
11:55 a.m.	Public Comment
12:00 p.m.	Adjourn

Call to Order

Michael Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 a.m.

Roll Call

MEMBERS IN ATTENDANCE

Steven Lane, Sutter Health, Co-Chair
Leslie Kelly Hall, Engaging Patient Strategy, Co-Chair
Ricky Bloomfield, Apple
Hans Buitendijk, Cerner
Grace Cordovano, Enlightening Results
Jim Jirjis, HCA Healthcare
Ken Kawamoto, University of Utah Health
John Kilbourne, National Library of Medicine
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
Brett Oliver, Baptist Health

Mark Savage, University of California, San Francisco's Center for Digital Health Innovation
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.
Daniel Vreeman, RTI International
Denise Webb, Indiana Hemophilia and Thrombosis Center

MEMBERS NOT IN ATTENDANCE

Aaron Miri, University of Texas at Austin, Dell Medical School and UT Health Austin

ONC STAFF

Michael Berry, Branch Chief, Policy Coordination, Office of Policy (ONC); Designated Federal Officer
Al Taylor, Medical Informatics Officer, Office of Technology

General Themes

TOPIC: REVIEW OF PHASE 1 WORK AND TF RECOMMENDATIONS TO HITAC

The USCDI TF 2021 reviewed Phase 1 of its work, which will culminate in a presentation by the co-chairs of the TF's recommendations to the HITAC on April 15, 2021. Copies of the recommendations were sent to TF members.

TOPIC: PHASE 2 AND 3 WORK AND TF SCHEDULE

The TF discussed its next steps, summer meeting schedule, and plans for Phase 2 and Phase 3 of its work. Recommendations from Phases 2 and 3 are due to the HITAC by September 9, 2021.

Key Specific Points of Discussion

TOPIC: USCDI TF 2021 HOUSEKEEPING

- USCDI TF 2021 meeting materials, past meeting summaries, presentations, audio recordings, and final transcriptions are posted on the new website dedicated to the TF located at https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force-2021
- The TF will continue to meet weekly on Tuesdays at the same time to discuss Phase 2 and Phase 3 of its work, and any breaks in the meeting schedule will be announced.

TOPIC: REVIEW PHASE 1 WORK

Steven and Leslie presented a review of Phase 1 of the USCDI TF 2021's work, which will be presented to the HITAC, and TF members were encouraged to attend the meeting/presentation. Phase 1 work included evaluating the draft Version 2 of the USCDI (USCDI v2) and providing the HITAC with recommendations by April 15, 2021, for:

- 1a - Data classes and elements from Version 1 of the USCDI (USCDI v1), including applicable standards version updates
- 1b - New data classes and elements from draft USCDI v2, including applicable standards
- 1c - Level 2 data classes and elements not included in draft USCDI v2

Steven summarized feedback that the co-chairs received on this work and stated that the TF made meaningful suggestions for an expansion of the draft Version 2 of the USCDI (USCDI v2), though some items suggested for inclusion by TF members and the public were not included. Some key topics TF will address with its Phase 1 recommendations and presentation to the HITAC included:

- Highlighting suggestions from CMS and the TF's related conversations

- The TF's discussion around data classes/elements at the intersection of HL7's Fast Healthcare Interoperability Resources (FHIR®) US Core, and HL7's Consolidated Clinical Document Architecture standard (C-CDA)
- Advancing social determinants of health (SDOH) data elements/class items from Level 2 to USCDI v2
- A request for ONC to contact HL7 to ask that work on implementation guides that support TF's suggestions for data classes and data elements will be prioritized consistent with the recommendation that certain data be included in USCDI only after the supporting implementation guides have been completed
- Asking the HITAC to weigh in on whether and how the TF should prioritize stakeholder feedback, going forward.

Steven stated that the HITAC will decide which TF recommendations will be sent to the National Coordinator for Health IT. Then, they will be considered for inclusion in USCDI v2, which will be published in July, 2021. Denise explained that a vote to forward the recommendations to the National Coordinator would be held at the HITAC meeting following the presentation.

TOPIC: PHASE 2 AND 3 WORK AND TF SCHEDULE

Steven discussed the USCDI TF 2021's next steps, summer meeting schedule, and plans for Phase 2 and Phase 3 of its work, which are due to the HITAC by September 9, 2021, and included:

- Phase 2: Evaluate the USCDI expansion process and provide HITAC with recommendations for:
  - o 2a - ONDEC submission system improvements (both the technical aspects of the system and the questions that are asked of submitters)
  - o 2b - Evaluation criteria and process used to assign levels to submitted data classes and elements
  - o 2c - Prioritization process used by ONC to select new data classes and elements for the subsequent draft USCDI
- Phase 3: Recommend ONC priorities for USCDI version 3 submission cycle

Steven asked Al to provide the list of questions used by ONC in the ONDEC system, and Al offered to share ONC's prep sheet and other criteria/questions. Leslie requested a process for evaluating where submissions were placed in the ONDEC ranking system (Comment Level, Level 1, Level 2). Al responded that this process currently takes place during back-and-forth negotiations/communications process between the submitter and ONC and offered to demonstrate the process, which would be part of Phase 2b work. Steven and Mark discussed their experiences submitting items and the interactive process of engaging with ONC.

Al displayed the leveling process matrix as well as the submission evaluation criteria ONC used when determining which submissions would be prioritized for inclusion in USCDI v2. Criteria for maturity were included, which took into account the current technical standards, current use in various environments, and current exchange availability (in electronic health record systems, in particular) and use cases, including the number of stakeholders impacted. Items ranked as Level 2 are available for inclusion in the next draft version of the USCDI.

Steven discussed the time sequencing and work involved in ONC's submission review process, and Al explained ONC's process for determining which submissions addressed significant existing gaps in the USCDI. He elaborated on prioritization criteria used for draft USCDI v2 submissions, which included:

- Level 2 data elements
- Significant gaps in USCDI v1 concepts
- Supported by existing ONC Certification
- Modest technical standards development
- Modest aggregate lift for vendor development and implementation, especially during pandemic

Al discussed how ONC has evaluated public comments on the draft USCDI v2 and how this has been part of the leveling and prioritization process. He described ONC's internal work process and emphasized that public comments remain available on the USCDI website. Communication with a submitter can change the leveling assignments, and ongoing work to further promote items within the USCDI can occur during the course of an annual cycle. Steven stated that the TF has been strict about not discussing items at the Comment Level or Level 1. Leslie clarified that public comments can amplify other comments and could possibly influence leveling.

DISCUSSION:

- In response to a question from Hans, Al stated that he would clarify in the future what, specifically, is meant by "an element of Standards Development Organization (SDO)-balloted technical specification" in the evaluation criteria document.
  - o Question: does this mean that the implementation guide or other specifications has completed the balloting process or just published, meaning the work is not completely finished?
  - o Andy suggested waiting until items are fully balloted and finished prior to including the relevant data in the USCDI.
  - o Mark discussed his experiences on a previous FACA and stated that there should be flexibility in high-need areas to push items forward instead of waiting for complete technical maturity.
  - o Al asked for clarification on Mark's comment and whether highly specialized items that only impact a narrow percentage of stakeholders should be bumped down the rankings. Mark stated that this is one example, but there is a range of other questions that could be used by the USCDI TF 2021 to determine how to prioritize items. He offered to share these past prioritization documents.
  - o Clem cautioned against waiting until an item is used by everyone; the TF could drive and encourage inclusion in USCDI and that such inclusion could drive the use of the relevant data. He asked the TF to prioritize data elements/classes from the clinical setting that are machine-produced and commonly exchanged, which do not require extra human labor (to enter data).
- Hans suggested that the TF/ONC should try to find a way to give the standards development community a longer lead time to prepare technical standards prior to the publication of each new version of the USCDI.
  - o Al stated that the prioritization criteria was not published until draft USCDI v2 was published, as ONC was still working on everything. A new version of the prioritization criteria (updated or just clarified) will be ready for publication when the final version of USCDI v2 is published. The TF can influence the criteria in this next version.
- Dan explained that terminology/vocabulary standards do not exist in a vacuum. They are tied to exchange standards, so the USCDI TF 2021 should have a conversation around the intersection of these standards with regard to ONC's prioritization criteria.
  - o Leslie suggested including this in Task 2b of the TF's future work.
  - o Al suggested that the TF could focus on the prioritization criteria (Task 2c) before its other tasks and deliver recommendations to the HITAC (which could then forward them to ONC) early. In response to Steven's request, TF members and ONC staff discussed how USCDI TF 2021 could reorganize its work schedule to present its recommendations for updates to the criteria to the HITAC at its July 2021 meeting, which would be in time to influence the prioritization criteria for the USCDI v3 submission cycle.
  - o Denise offered to facilitate this work and get the presentation to the HITAC scheduled.

- o Clem, Hans, and other TF members supported these suggestions. The request will be made by the TF co-chairs during their presentation to the HITAC.
- Clem shared additional information and requested to change the level for tonometry from Level 1 to Level 2 for USCDI v2. Steven suggested that Clem could voice such a suggestion during the HITAC meeting on this item.
- Steven asked Al to comment on how ONC's public and private meetings with stakeholders will be used to influence what is included in USCDI v2. Steven had previously stated that only publicly submitted comments and HITAC recommendations would be considered.
  - o Al stated that the following forms of feedback will be considered: public comments on individual data classes and elements from the submitters, clarifications/edits to submissions, HITAC recommendations, and public comments made on the general USCDI webpage. Al discussed how comments and edits to submissions might change the assigned level for an item.
- Al commented on ONC's process to weigh submissions by stakeholders and stated that they recognize the authority and expertise of stakeholders over their submissions/comments.
  - o Leslie stated that there is no natural sponsor or advocate to represent patient concerns that has the gravitas of other stakeholders. She hopes that the HITAC would consider elevating and supporting comments on behalf of patient interests.
  - o Al stated that individual comments are not discounted by ONC while supporting the suggestion that the HITAC and others can raise the awareness/profile of these comments.
  - o Steven commented that he met with the ONC team as a member of the earlier version of the USCDI TF. During this time, the former TF co-chair, Terry O'Malley, was a staunch advocate of one of the previous TF's guiding principles that anyone (not just larger organizations or players in the industry) could submit comments and suggestions for data elements.
  - o Steven displayed a draft of an updated set of guiding principles and methodology for the USCDI TF 2021's Phase 2 work and asked for TF member feedback.
- Leslie suggested distributing a survey through the Electronic Health Record Association (EHRA) to various stakeholders to learn about what data requests are most often made by patients/individuals, which items are most often misunderstood, and where functionality in patient portals may be lacking. Also, survey questions could address where there is a high volume of work being done in portals and what specific types of data are being accessed.
  - o Sasha stated that the EHRA could query its members, and reported that surveys have been done in the past to assess EHR developers' knowledge of interoperability usage of their products. However, she suggested that some of the questions Leslie listed should logically go to provider organizations, like those around the frequency of use of specific data.
  - o Hans agreed that having a provider perspective, in combination with what data are currently being queried, would be helpful. Surveys have not been done in some time and could be updated now.
  - o Grace shared a list of types of critical information patients need, which included: the need to make new/second opinion appointments, to appeal insurance denials, to submit and manage disability applications, and to apply for clinical trials.

Action Items

As their homework, USCDI TF 2021 members were asked to review ONC's prep sheet and come to the meeting with suggestions for how to improve it from a content and technical perspective (Task 2a). The prep sheet is located at: https://www.healthit.gov/isa/ONDEC. TF members are also asked to review the leveling criteria (Task 2b) and prioritization items (Tasck 2c).

TF members will prepare for work on Phase 2 tasks and will send questions and feedback to the TF co-chairs.

TF members were encouraged to review meeting materials on the TF website at
https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force-2021

Public Comment

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

There was one public comment received via phone:

Viet Nguyen, MD, of the HL7 Da Vinci Project: Thank you for all of the hard work you are doing. This is really great. I apologize, we should have participated more frequently before. Thank you for the opportunity to provide comments on behalf of the HL7 Da Vinci project. For those who do not know me, I am the technical director for the Da Vinci Project. We submitted six submissions for inclusion in USCDI. I wanted to highlight three of them in a short amount of time. One, is not knowing where you adjudicated all of these. We have strong support from our members around the insurer information of the member/patient and identifiers such as Subscriber ID, Member ID, and Plan Information. We think it is important in terms of including this data in patient matching and the use of deterministic approaches, as opposed to other approaches. We think it is important to we recognize some of these administrative standards were not necessarily in USCDI version 1, and we hope to see them in the next version. Next, is that Medication Dispense information, as part of the Medication data class. It is important that providers know that patient not only received a prescription for a medication/order, but at least we know they have the medication, whether or not it is taken is a separate issue. It is an important aspect of doing patient management and population management. Lastly, I want to discuss the Provider Identifier (NPI). We are in strong support of including the NPI, as well as DEA numbers, to the extent they are used by a subset of providers to help identify providers. Those are the two that we felt fairly strongly about. There are others that are more complicated. We submitted a request around Provenance, so that we could identify and use a set of profiles, extensions, and value sets to identify where data comes from since they are not always going to be in FHIR. Maybe that will be in version 2 or version 3. That would be important for receivers of information. We also made a request around Medical Record Numbers. I know there is no particular standard for that one, but it will help with patient matching, as well. Then, finally, Devices and being able to support not only clinical devices, but codes for devices that are durable medical equipment, or oxygen or other things that would track the use of medical devices. My time is up. I want to respect that. Thank you for the opportunity to comment. We will submit comments on the website, too. Thank you.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

Mike Berry (ONC): Good morning, and welcome to the USCDI task force. We will be getting started shortly.

michelle schreiber: Mike - hi. this is Michelle Schreiber from CMS. I apologize but I will need to leave the meeting quite early due to another conflict.

Leslie Lenert: Leslie Lenert is here

Andy Truscott: I'm here – won't be talking much - new flooring going in in the background!

Clement McDonald: I am here too. Clem

Jim Jirjis: Jim Jirjis Here

Steven Lane: https://www.healthit.gov/isa/ONDEC

Viet Nguyen, MD (HL7 Da Vinci Project): It is very helpful to see the comments submitted on the individual Data Element pages on USCDI V2 Draft page. Additional information about how the comments are being adjudicated (especially if a final/near-final decision is made) is very, very helpful. Knowing

where we can reinforce or add comments would help us direct comments to where they are most useful. Thank you!

Leslie Kelly Hall: @Viet On the public submission site you can voice comments on others'; submissions to amplify your voice.

Viet Nguyen, MD (HL7 Da Vinci Project): Terminology has less of an issue with balloting/publishing, compared to an implementation guide (e.g FHIR IG)

Viet Nguyen, MD (HL7 Da Vinci Project): @Leslie - Thank you. I would appreciate a few minutes. I'm on the phone and online. I'll be ready towards the end of the call.

Leslie Kelly Hall: @ viet public comment 1877 407 7192
Viet Nguyen, MD (HL7 Da Vinci Project): @Leslie - Yes. That's the line I'm on

Viet Nguyen, MD (HL7 Da Vinci Project): Please don't let my comment disrupt your course.

Clement McDonald: Dan makes a very important point. They are like love and marriage, horse and carraige (as in the sogn) *[sic]* they just have to go together

Grace Cordovano, PhD, BCPA: Sounds like a great plan!

Jim Jirjis: agree

Al Taylor, ONC: i just got kicked off the call. reconnecting now.

Viet Nguyen, MD (HL7 Da Vinci Project): @Al - Thank you for the explaination. *[sic]* How do you view submissions from industry organizations (like Da Vinci) vs individuals or entities?

Grace Cordovano, PhD, BCPA: That is an important clarification

Mark Savage: Yes, important clarification.

Viet Nguyen, MD (HL7 Da Vinci Project): @Al - Thank you again.

Mark Savage: Yes, Eiffel!

Mike Berry (ONC): We will open the line for public comments soon. Comments are limited to 3 minutes per person. To make a comment please call: 1-877-407-7192 (once connected, press "*1" to speak).

Hans Buitendijk: Agreed with these questions *[sic]* need to be addressed to establish a balanced push/pull of moving USCDI forward.

Jim Jirjis: Wonder if we should consider data elements that assist with sharing full EHI...the gap between whatever version of USCDI we will have and what is in the designated record set

Sasha TerMaat: Jim, I agree that will be important.

Jim Jirjis: could help make sharing EHI less burdensome

Leslie Lenert: I'd like to enthusiastically endorse the last comment: We need to focus on the adequacy of USCDI based on mapping against specific use cases as described!

Leslie Kelly Hall: Agreed @ Les and Grace

Leslie Kelly Hall: @JIm great point

Leslie Kelly Hall: Thanks @viet

Jim Jirjis: yes

Jim Jirjis: thank you

Viet Nguyen, MD (HL7 Da Vinci Project): Thank you for the opportunity and for all your hard work!

Resources
USCDI TF 2021 Website
USCDI TF 2021 – April 13, 2021 Meeting Agenda
USCDI TF 2021 – April 13, 2021 Meeting Slides
USCDI TF 2021 – April 13, 2021 Webpage
HITAC Calendar Webpage

Adjournment
Steven thanked everyone for their work at the current meeting. The USCDI TF 2021 will hold its next meeting on Tuesday, April 20, 2021.

The meeting was adjourned at 12:00 a.m. E.T.