Health Information Technology Advisory Committee

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

Meeting Notes | April 20, 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 begin Phase 2 of its work, which will culminate in one or more presentations by the co-chairs of the TF's recommendations to the HITAC at future meetings. The TF discussed its next steps and plans for Phase 2 of its work (Tasks 2 and 3) and predominantly focused on how the TF could update the prioritization criteria used by ONC to select data elements and classes for inclusion in the USCDI (Task 2c).

There were no public comments submitted by phone, but 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 TF Recommendations to HITAC
10:50 a.m.	Phase 2 Kickoff Discussion
11:50 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
Ken Kawamoto, University of Utah Health
John Kilbourne, Department of Veterans Health Affairs
Clem McDonald, National Library of Medicine
Brett Oliver, Baptist Health
Mark Savage, University of California, San Francisco's Center for Digital Health Innovation
Abby Sears, OCHIN

Sasha TerMaat, Epic
Sheryl Turney, Anthem, Inc.
Daniel Vreeman, RTI International
Denise Webb, Indiana Hemophilia and Thrombosis Center

MEMBERS NOT IN ATTENDANCE

Jim Jirjis, HCA Healthcare
Les Lenert, Medical University of South Carolina
Aaron Miri, University of Texas at Austin, Dell Medical School and UT Health Austin
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Andrew Truscott, Accenture

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 co-chairs briefly summarized the TF's presentation to the HITAC and the vote on the TF's recommendations.

TOPIC: PHASE 2 KICKOFF DISCUSSION

The USCDI TF 2021 discussed its next steps and plans for Phase 2 of its work. Recommendations from Phases 2 are due to the HITAC by September 9, 2021, but some TF Tasks might be completed at an earlier date and presented to HITAC, pending ONC feedback.

Key Specific Points of Discussion

TOPIC: USCDI TF 2021 HOUSEKEEPING

- Steven announced that Abby Sears, CEO at OCHIN, has joined the TF. She introduced herself and discussed her experiences as a member of the HITAC, background, recent work, and issues OCHIN has prioritized, including health equity, exchanges of data, electronic case reporting, social determinants of health (SDOH) data, and the movement of diagnostic information.

- The public comment period for the draft of version 2 of the USCDI (draft USCDI v2) closed on April 15, 2021. ONC is working to evaluate and categorize the submitted comments, and Al discussed the process ONC is using to determine what will be included in the final version of USCDI v2. Comments entered into the submission system from April 15 through September 2021 (the closing date has yet to be announced) will be considered for the USCDI v3 submission cycle. The final USCDI v2 will be published in July 2021. Updates to the evaluation and prioritization criteria will be published around the same time.

- USCDI TF 2021 meeting materials, past meeting summaries, presentations, audio recordings, and final transcriptions are posted on the 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 of its work, and any breaks in the meeting schedule will be announced.

TOPIC: REVIEW TF RECOMMENDATIONS TO HITAC

At its April 15, 2021 meeting, the HITAC voted unanimously to accept the recommendations put forward by the USCDI TF 2021 on Phase 1 of its work. Now, the TF's recommendations will be transmitted to the National Coordinator for Health IT. Then, they will be considered for inclusion in USCDI v2, which will be published in July 2022. Steven and Al gave an overview of discussions that have been held with ONC around the general scope and purpose of the USCDI. The USCDI TF 2021 co-chairs will continue to discuss these
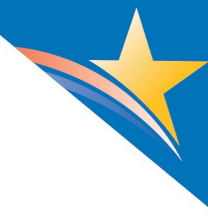
topics with Micky Tripathi, the new National Coordinator for Health Information Technology, and the team at ONC shortly.

At its April meeting, Leslie had asked the HITAC to weigh in on how the TF should move forward with regard to prioritizing different groups of stakeholders in its future work. Leslie stated that the TF did not get strong feedback on this topic but thanked Abby for her comments. Denise suggested that there was no opposition from the HITAC to the TF's work but added that the HITAC did not directly address how/should certain stakeholders be prioritized. Denise added that the task force is at liberty to include recommendations regarding stakeholder prioritization in its presentations to HITAC as a part of its work on the assigned tasks.

TOPIC: PHASE 2 KICKOFF DISCUSSION

Steven discussed the USCDI TF 2021's next steps and plans for Phase 2 of its work. It was previously announced that the TF's responses to the remaining tasks would be due to the HITAC by September 9, 2021, and included:

- Task 2: Evaluate the USCDI expansion process and provide HITAC with recommendations for:
  - o 2a - ONDEC submission system improvements
  - 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 draft USCDI v2
- Task 3: Recommend ONC priorities for USCDI version 3 (USCDI v3) submission cycle

In response to a question from Mark, Al explained that ONC is planning on issuing a Standards Bulletin containing any changes to their level evaluation criteria and Level 2 data element selection prioritization criteria in early July 2021, and that ONC is interested in TF/HITAC recommendations on these topics to better inform this publication. The publication would also coincide with ONC's publication of the final USCDI version 2. As a result of these announcements, Steven suggested that the TF begin its Phase 2bwork focusing on Tasks 2b and 2c and complete this work in time to present recommendations to the HITAC at its June 9, 2021 meeting. Then, the TF can return to focus on Tasks 2a and 3 to meet the September 9, 2021 deadline.

Mark shared information he prepared on a wider overview of the USCDI and its future use cases. He discussed national use cases that depend on the USCDI and stated that it serves myriad needs simultaneously. A list of examples was included in a presentation he developed with the Center for Digital Health Innovation (CDHI) as UCSF. He discussed how these use cases enable opportunities in digital quality measures, interoperability, health equity, COVID-19 relief efforts, and more. He described CDHI's strategic priorities for the delivery of care, for patients and family caregivers, and for shared decision-making by providers, patients and family caregivers working as partners. He stated the examples included in his presentation materials was illustrative and not meant to be exclusive.

Mark discussed his previous work in 2015 with the Advanced Health Models and Meaningful Use Workgroup of the Health IT Policy Committee. The workgroup created a framework for evaluating interoperability use cases. He suggested that the USCDI TF 2021 could build on the prior workgroup's framework and stated that a similar framework could be used to evaluate Level 2 data elements for inclusion and to identify Level 1 data elements that deserve additional consideration. The impact of the data elements would be evaluated along multiple dimensions including their impact on the three pillars of the Tripple Aim, health, care, and cost/value. ACHE of MAa classes/elements could also be evaluated based on identified national programmatic needs (e.g., the National Quality Strategy and Nationwide Interoperability Roadmap) as the previous workgroup suggested,to determine how each data element would fit into the national ecosystem. Finally he suggested that data elements could be evaluated and rated according to various subdomains of operational readiness and beneficiary net impact. The TF discussed the proposed evaluation methodology and how such a system might support ONC's work to review data classes and elements submitted through the ONDEC system.

Steven discussed ONC's current criteria for leveling data classes and elements as Comment level, Level 1, or Level 2 and asked the TF to consider if the criteria for bringing items to Level 2 is appropriate for the V3 submission cycle or if it should be modified. He invited the TF to discuss whether it is appropriate for an element to be specified as core to nationwide interoperability if its technical or operational maturity falls below

the current requirements for Level 2. The TF's previous discussions around how ocular tonometry should be leveled are an example of how the ONC's proposed item leveling methodology could be debated and potentially changed. Al confirmed that additional input, public comment, submitter clarifications, and other interactions with the submitter(s) could result in ONC re-leveling/re-categorizing a data element/class. The timeframe for this reconsideration process is before the drafting of the subsequent version of the USCDI. In these cases, ONC might consider additional information that would improve the quality (and leveling) of the element. Al stated that, as part of its work, the TF could submit recommendations to the HITAC/ONC to clarify the leveling process.

Steven reviewed the evaluation criteria for leveling and prioritization for draft USCDI submissions and asked TF members to submit feedback on how these could be optimized. The original wording for prioritization criteria 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 the pandemic

The co-chair emphasized that some or all of the items in the prioritization criteria list could become and/or (i.e., some conditions must be met, in addition to or instead of others) items, which could help weight data elements/classes in the prioritization process.

DISCUSSION:

- Grace asked if the USCDI TF should reexamine and adjust its work to prioritize data that will be most important to patients in light of a post-COVID-19 pandemic ecosystem.
  - o Steven responded that the criteria established for USCDI v2 may be different from those for v3 and future versions. The TF should focus on current concerns and not try to anticipate future concerns; criteria will continue to be updated in a dynamic process to address future concerns.
  - o Al agreed that there will be room to adjust the criteria and the TF's processes in the future.
  - o Leslie agreed that the TF should address current pressing concerns.
  - o Grace asked how data classes and elements that are essential to the pandemic/post-pandemic world can be promoted in the USCDI, even if they do not have standards or implementation guides (IGs) associated with them.
  - o Steven responded that the TF's criteria was to work on "modest technical standards development" and noted that the TF has not held the need to have an IG or standard associated with a data class or element as criteria for inclusion in the USCDI.
  - o Al responded that ONC has stated that an element/class needs to be usable/represented by a terminology standard or IG as criteria for inclusion in Level 2.
  - o Leslie stated that some data element/classes have been included in USCDI before standards were fully developed, and they then drove the definition and finalization of standards needed for those data to be ready for use. There is give and take, and the TF should discuss updating recommendations around this process.
  - o Clem cautioned the TF against accepting narrative content that is unstructured/without requiring some associated standards, as it is difficult to exchange it electronically. He suggested that the TF prioritize items that are already supported and being shared. This could motivate those who regularly use content that is unsupported to get it into a format that can be shared/used by others. The Gravity Project has focused on this work. He also warned against over modeling, which creates more work for developers and users.

- o Steven reiterated Clem's previous point that data that are already being exchanged today should be considered for inclusion. ONC's criteria for an item to be included in Level 2 is that it must be represented using a terminology standard or be an element of a balloted technical spec. Grace's point was that there are items that are being used (and would be useful for patients), but that are not exchangeable/at this level of technical maturity as currently required for inclusion in the USCDI.
  - o Hans agreed with other commenters that Level 2 items may not need to have a full set of implementation guides. However, because the USCDI is used for certification, there should be an understanding that anything designated as Level 2 will eventually need to be supported technically. If a data element/class is designated as Level 2, standards bodies might be pushed into creating a definition.
  - o Abby suggested that the first strategic priority (around delivery of care) should call out mental health referrals and mental health components, specifically, as part of supporting continuity of care.
  - o Steven reminded TF members that comments and recommendations to the HITAC will be on the leveling process as well as the criteria used to prioritize Level 2 items for inclusion in USCDI.
- Leslie thanked Mark for sharing the Advanced Health Models and Meaningful Use Workgroup's previous evaluation and prioritization framework. She emphasized the importance of conversations the workgroup had around beneficiary net impact, which helped identify the stakeholders that would benefit and guided the workgroup's prioritization.
  - o Steven noted that the previous framework was supported by a weighting system and asked Mark and/or ONC to comment on the final practical usefulness of the framework.
  - o Mark stated that the workgroup presented to ONC's Policy Committee. Previous workgroup conversations helped to identify priorities before the presentation to ONC, so the workgroup's presentation seemed to be useful to ONC.
  - o Leslie explained that having a common framework would allow for a stronger due diligence process when evaluating proposed data elements.
  - o Al stated that he has not seen any direct follow-up analysis of the impact of the work.
  - o Steven responded that some of the workgroup's underlying principles (technical readiness, operational readiness, evaluating the impact on stakeholders) are reflected in ONC's current submission evaluation criteria. A variation on the existing less complex and laborious process may be more useful going forward as the number of proposed data elements has increased well beyond the 50+ use cases that the earlier WG's method was designed for.
  - o Abby emphasized that ONC's work will set the tone for the rest of the U.S. and stated that the tone should prioritize equity in healthcare. The TF should find a balance as far as how mature data elements are versus how necessary they are for promoting health equity. If the TF does not push ONC to set the tone, who will do it?
- Grace asked why advanced directives and end-of-life care were still at Level 1 and if there were not enough standards in place to move the classes/elements forward.
  - o Al responded that the consensus about which standards to use or other factors (missing information, "mislabeling," etc.) could be missing for these items. Therefore, they might have been assigned to a lower level. ONC invites public commenters, Stakeholders and submitters to weigh in with additional information early in each submission cycle in order to better influence the process. This must be done before the publication of each year's draft.
  - o Dan reminded TF members that the ONC's submission framework and evaluation process is still in its early stages, so there is time to change it. Though the process allows for anyone to submit a data class or element, a larger community (beyond the submitter) needs to take action to appropriately level an item.
- Grace suggested that the USCDI TF 2021 examine how the COVID-19 pandemic shaped prioritization and determine if it was given a great enough emphasis on its impact on data classes/elements under consideration, especially given the success of vaccines.
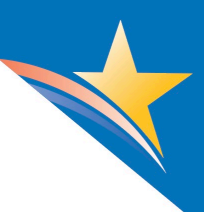
- Abby asked how the TF should handle the issues that have recently proven challenging in the U.S., especially related to the lack of emphasis around equity issues, public health, and mental health if the TF sticks to the requirement for data maturity. The challenge is that some items that are the most needed, in light of the pandemic, are some of the least developed in terms of standards maturity. She agreed that the prioritization criteria seem reasonable but warned the TF that they risk continuing to underserve populations that are already underserved in terms of data.
  - o Leslie agreed that this is a challenge and stated that no one organization represents or shepherds the needs of the data-underserved populations through standards bodies. Guidance is needed, and, perhaps, the needs of certain stakeholder populations could be weighted for emphasis.
  - o Clem suggested that commenters should be specific with their requests for how data under-served populations could be helped.
  - o Mark suggested that the TF should pose the question, "Where do we need to be, as a national ecosystem?" in order to determine what should happen next.
  - o Al stated that there is a difference between these prioritization criteria, which were designed to help ONC select from the data elements for addition to USCDI v2, and the concerns that were raised by TF members about which specific data elements should be submitted.
  - o Steven stated that the discussion by TF members and summary of the previous workgroup's framework highlighted the need to recognize the underrepresented data, under-served stakeholders, and other gaps in the nationwide ecosystem. He suggested that the TF add an additional bullet to the prioritization criteria to serve as a form of affirmative action or advocacy for current/topical categories. He asked the TF to consider how to frame updates to the prioritization criteria.

Action Items

As their homework, USCDI TF 2021 members were again asked to review the evaluation criteria for leveling and prioritization for draft USCDI submissions. TF members will prepare suggested changes to both the evaluation criteria and the prioritization criteria and will come to the next TF meeting prepared with specific recommendations and points for discussion.

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 were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT
Mike Berry (ONC): Good morning, and welcome back to the USCDI Task Force meeting. We will be getting started soon.

Clem McDonald: I am here –Clem

Abby Sears: I am here as well

Clem McDonald: Is any of that experience published or available. Is is only Medicaid data ?

Abby Sears: We have lots of published articles. We have a research division. It is predominantly Medicaid but we also have Medicare and lots of uninsured. I have given presentations on much of this so I have the data if we want to look at it at some point.

Sheryl Turney: I am on sorry had trouble getting in today.

Denise Webb: I need to step away from the call 10-10:30 CT and will return for last 30 min.

Sheryl Turney: thank you for moving the SDOH to Level 2

Hans Buitendijk: Part of the challenge is that having vocabulary is not enough to enable interoperability consistently. The implementation guides are essential for that. So shouldn't a Level 2 be vocabulary and implementaiton *[sic]* guide?

Grace Cordovano, PhD, BCPA: Is there a global reference or link listing terminology standards, SDO-ballotted *[sic]* technical specifications, applicable standards, etc that the public can refer to when submitting data elements and classes in USCDI ONDEC?

Hans Buitendijk: @Grace: The ISA has many of them, but may not be current on all work in progress that may have advanced enough to be reasdy *[sic]* and in use in time to be considered.

Clem McDonald: there is lots of interest in ascertaining the causes/resaons *[sic]* for health disparities and missing racial data that may distort the Have to be careful about requiring implementation guides to specifically. Some general implementation guides such as CDA, V2 and FHIR observation carry the great majority of health care interesting data. When one gets to modeling each little subset of data it becomses *[sic]* too much work for all.

Grace Cordovano, PhD, BCPA: Will add disability applications and appeals processes also will rely heavily on data from USCDI, especially in our pandemic/post-pandemic world.

Steven Lane: Grace - You may want to connect with the team at SSA that has done a LOT of work specifying the data required to support disability applications and are just now ready to pilot the use of FHIR to collect this data from providers.

Hans Buitendijk: @Clem - Agreed that we don't need to over model, but there needs to be agreement on where and how to communicate the data as consistent as necessary..

Daniel Vreeman: Totally agree with Clem on the over-modeling point. An agreed FHIR profile for Obserservation *[sic]* bound to a standard terminology (i..e LOINC) would go a really long ways.

Clem McDonald: Mental health communication faces special legal strictures - have to consider that in the process

Abby Sears: We have made great inroads into the protections around the mental health data having them move to the HIPAA rules. I agree we need to pay attention but it is gettingn *[sic]* easier especially with the new rules around consents.

leslie kelly hall: So much can be learned in behavioral health without notes and without the more difficult privacy issues. correct @abby?

Clem McDonald: lets highlight that. Because holder get very nervoous *[sic]* about the highly protected data in case they make mistakes

Abby Sears: Yes and if the data is now being governed by HIPAA. The data needs to be treated the same way as all of the other data.

leslie kelly hall: Yes @Abby!

Grace Cordovano, PhD, BCPA: When looking at the Submission Evaluation Criteria, is there a role for the TF in assessing and weighing the risks/benefits of selecting particular submissions?

Mark Savage: Yes, this framework gives equal consideration to need, to impact, as to maturity, and tries to consider them together.

leslie kelly hall: @grace we can in our prioritization process to address this

Denise Webb: I am back

Abby Sears: I guess my question is how do we handle the issues related to the lack of emphasis around equity issues that we have been challenged with as a Country if we stick to the requirement for maturity

Grace Cordovano, PhD, BCPA: +1000 Abby

Mike Berry (ONC): We welcome public comments and will open the line for comments soon. To make a comment please call: 1-877-407-7192 (once connected, press "*1" to speak).

Grace Cordovano, PhD, BCPA: It would be helpful if the Prioritization Criteria reflected submissions by stakeholder.

leslie kelly hall: Perhaps there is a bullet for the data underserved tat *[sic]* allows for development on a specific use case

Grace Cordovano, PhD, BCPA: Foe example, vice president, Kamala Harris is calling for sweeping action to curb racial inequities in pregnancy and childbirth; just one example of an initiative..

Abby Sears: I commit to spending real time on suggestions related to this.

leslie kelly hall: Thank you Abby!

Joel Andress: You need your priorities reflected in both the prioritization and leveling. While certainly, you want to push development of relevant standards to an acceptable level of standardization, you will drive that most effectively by demonstrating that such efforts will have relevance in future policy and programmatic requirements.

Sheryl Turney: thank you Steven for your leadership

Resources
USCDI TF 2021 Website
USCDI TF 2021 – April 20, 2021 Meeting Agenda
USCDI TF 2021 – April 20, 2021 Meeting Slides
USCDI TF 2021 – April 20, 2021 Webpage (for additional resources)
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 27, 2021.

The meeting was adjourned at 11:59 a.m. E.T.