

Health Information Technology Advisory Committee U.S. Core Data for Interoperability Task Force 2021 Virtual Meeting

Meeting Notes | April 27, 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 two presentations by the co-chairs of the TF's recommendations to the HITAC at future meetings. Brett Marquard and Wayne Kubick presented HL7's U.S. realm perspective on USCDI changes. The TF began work on Tasks 2b and 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 Call10:35 a.m.Past Meeting Notes10:40 a.m.HL7® US Realm Perspective11:00 a.m.Tasks 2b and 2c11:50 a.m.TF Schedule/Next Meeting11:55 a.m.Public Comment12:00 p.m.Adjourn

Call to Order

Cassandra Hadley, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:33 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 John Kilbourne, Department of Veterans Health Affairs Clem McDonald, National Library of Medicine Brett Oliver, Baptist Health Abby Sears, OCHIN Sasha TerMaat, Epic Sheryl Turney, Anthem, Inc.



Denise Webb, Indiana Hemophilia and Thrombosis Center

MEMBERS NOT IN ATTENDANCE

Ken Kawamoto, University of Utah Health Les Lenert, Medical University of South Carolina Aaron Miri, University of Texas at Austin, Dell Medical School and UT Health Austin Mark Savage, University of California, San Francisco's Center for Digital Health Innovation Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS) Andrew Truscott, Accenture Daniel Vreeman, RTI International

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: HL7® US REALM PERSPECTIVE ON USCDI CHANGES

Brett Marquard and Wayne Kubick presented HL7's U.S. realm perspective on USCDI changes.

TOPIC: USCDI TASKS 2B AND 2C

The USCDI TF 2021 focused on Phase 2 of its work. Recommendations from Tasks 2b and 2c will be presented to the HITAC on June 9, 2021, and the other Tasks are due and will be presented at the HITAC's September 9, 2021 meeting.

Key Specific Points of Discussion

TOPIC: USCDI TF 2021 HOUSEKEEPING

- 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. The TF's recommendations have been transmitted to the National Coordinator for Health IT. Then, they will be considered for inclusion in USCDI v2, which will be published in July 2021.
- 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. 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 <u>https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force-2021</u>
- 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: HL7® US REALM PERSPECTIVE ON USCDI CHANGES

Steven explained that the USCDI TF 2021 recommendations to the HITAC supported the inclusion of certain data elements in USCDI v2 only if the implementation guides (IGs) and standards supporting them are at a level of completeness for vendors/the industry to be able to exchange the data meaningfully. The entire class of social determinants of health (SDOH) data elements were among these, as well as sexual orientation and gender identity (SOGI) data, and, because they have generated a lot of support from ONC and HITAC members, the TF co-chairs asked HL7 to present its perspective on how standards and IGs (US Core, C-CDA) will support changes to the USCDI and how taskforce recommendations and changes to USCDI will

determine HL7's priorities and work. Brett Marquard and Wayne Kubick introduced themselves and presented HL7's U.S. realm perspective on USCDI changes.

Wayne stated HL7 is a consensus-based standards organization that is accredited by the American National Standards Institute (ANSI). He described how HL7 develops standards and a flow chart for HL7s project scope statement (PSS) process, including the steps for creation of content, balloting, reconciling comments, and publishing was included on slide #2 of the presentation materials.

Brett stated that US Core is the HL7 IG that most closely maps to the USCDI, though they do not match completely (US Core is bigger than the USCDI). He described the journey to US Core, adding that there is a high bar for publication in US Core, which was depicted on slide #3 in the presentation. He stated that ONC, CMS, and others can short-circuit the process through rulemaking. He discussed steps in the US Core Road Map, which was depicted on slide #4 and covered the time period from January 2020 through December 2022. He explained that the ultimate goal, once the process has been refined, will be to ballot the US Core every January and publish the new release every May. He emphasized the importance of testing and piloting work to create good standards for deployment into the ecosystem.

Wayne added that HL7 has a requirement that FHIR IGs go through at least one Connectathon before balloting. This requirement impacts the timeline.

Steven discussed the "chicken and egg" issue of the USCDI TF 2021 recommending that four data classes/elements – Discharge Medications, SOGI and data elements under Patient Demographics, Medicare Beneficiary ID (MBI), and SDOH. These recommendations were contingent on HL7 supporting them in their IGs. However, HL7 has stated that they will complete their work on elements once they are included in USCDI. He suggested that HL7 and the USCDI TF should work to be more closely connected with their goals and invited the presenters and TF members to engage in a discussion session on these topics.

DISCUSSION:

- Brett M. summarized HL7's recent work on the four data classes/elements in the TF's recommendations
 and discussed the likelihood that they would be included in the next publication of US Core in May 2021:
 - The Discharge Medications data class has a clear definition, so it seems likely that HL7 will be able to add guidance for this data class in the upcoming publication (in time for inclusion in USCDI v2).
 - The SDOH, MBI, and SOGI elements are dependent on the clarity of the requirements and how they are used/captured in clinical care. When this is clear, the standards process can move quickly. He stated that the SDOH elements are a large topic and might require extra design work on HL7's side, so they might not be ready (from HL7's perspective) until the publication of Version 3 of the USCDI (USCDI v3) in 2022. If the TF begins a process to propose/forecast their recommended elements in advance, HL7 will be able to better anticipate and prepare for them.
 - Steven responded that Hans has shared these suggestions with the TF and explained that they have received suggestions that the TF create a multi-year roadmap to identify its recommendations for future update cycles.
 - Wayne stated that HL7's planning and scheduling process of determining which items are mature enough for inclusion is impacted by the publication date of the next version of the USCDI.
- Leslie thanked the presenters for the clarity and for suggesting ways in which the TF can better send signals or share recommendations with the industry. She stated that the California Health Information Exchange (CAHIE) Association recently told her that when whole data classes are considered for inclusion, not just single data elements (especially provider data and patient demographics), it is an easier lift for their overheads for extracting/reporting. She asked how HL7 approached data classes vs. elements.
 - Brett M. responded that it is easier for HL7 to design a framework if they have a data class that has example elements included with it. He explained how HL7 designs a framework. It is better if the USCDI TF shares examples of elements as a way of providing guidance for a data class.
 - O Steven suggested that a data class might never be complete; new elements can always be added.

- Wayne explained that data class usually matches with a FHIR resource, which breaks into "resources" and terminologies that are assigned to them. Classes are easier because they are much less specific, though both are needed. He reiterated that examples are helpful.
- Clem encouraged everyone not to be stingy when making recommendations about elements and classes for inclusion. Also, he asked if Clinical Reports and Imaging Reports would also be priorities, as they bring value to clinical care, and added that they could both include narrative pieces.
 - Brett M. responded that Imaging Report was added in the last update cycle, and Imaging Narrative is also included. Clinical Reports could be absorbed easily. Also, he explained that HL7 includes Goals (as a resource) but added that, while it is important, he does not understand exactly how it is used in clinical care today.
- Clem commented that SDOH data used to be gathered by asking a patient 20 (or so) questions, but now there are additional resources attached, which make the collection more complicated and potentially burdensome. Why has this changed?
 - Leslie responded that this depends on what information is already being collected, what information is new, and who is doing the collecting. Workflows for SDOH are still being worked out, but she emphasized the importance of this area for providing value-based care. Aspirational goals are important in this area, even if more work is needed. She thanked the Gravity Project for its contributions.
 - O Steven responded that a tremendous amount of work has been done on SDOH over the past years through Connectathons, and the Gravity Project has submitted many SDOH data elements through ONC's New Data Element and Class (ONDEC) submission system. ONC leveled five of these elements as Level 2, meaning they were felt to be technically ready for inclusion in a future version of USCDI. These included Assessment, Problems/Health Concern, Interventions, Goals, and Outcomes. He was surprised to hear HL7 say that not enough work has been done on SDOH, based on ONC's leveling, and inquired about what is missing from these five elements.
 - Brett M. agreed that they are important but stated that, though HL7 has guidance on some of the elements, the broader question is whether they are ready to be used in real-world, clinical care settings. HL7 will look to the Gravity Project and EHR vendors for more information.
 - Leslie commented that this is the chicken and egg problem again. There is an obligation to move forward on these SDOH elements, somehow.
 - Wayne responded that there are existing buckets where these elements could be placed (except for Outcomes) in HL7, but they might not have sufficient examples or value sets defined with controlled terminologies. There are FHIR resources that can be used for these elements.
- Jim asked the presenters about extending the notes categories in the standards and HL7's plan to do so in the future. He listed several specific types of notes.
 - Brett M. responded that the design framework for notes is clear, but some of the elements Jim mentioned (advanced directives and functional status) may not fit into Clinical Notes and would need a more complex process.
 - Jim confirmed that clear note categories (like the new Narrative Operative Report) are easier to absorb, and Brett M. agreed.
- Abby commented that states are starting to require the capturing of SDOH data, and that different states
 require different types of data to be captured in a variety of workflows. She emphasized the inefficiencies
 and expenses related to this approach and inquired about pathways to speed up work to support the
 capturing and sharing of standardized SDOH data.
 - Steven agreed with Abby's comments and stated that the USCDI TF should channel the enthusiasm from COVID-19 relief effort work to move the class of SDOH forward with USCDI v2, including the elements that have enough structure. Other data elements can be added in future USCDI versions as they reach an appropriate level of maturity.

- Leslie commented that the new administration has emphasized issues related to equity and suggested that the TF and HL7 should consider reprioritizing their work to capitalize on this support and momentum in the current political climate. She stated that equity issues have existed for at-risk patients for years, and the TF and HL7 have an opportunity to address them.
- Grace thanked Brett M. for sharing HL7's roadmap, which helped illustrate the amount of time necessary to move items forward. She stated that the TF's charge/task is to address significant gaps in the USCDI and emphasized that they should try to look at these gaps from the patient/care partner perspective, as they are the most data underserved population of stakeholders. The TF needs to discuss the prioritization of high-use elements that do not have supporting/mature technical standards.
 - Steven commented that the TF needs to consider if it is appropriate to make recommendations to the HITAC and ONC if the recommended classes/elements are not fully supported by technical standards. He asked the presenters how HL7 would respond to recommendations from HITAC/ONC for these types of items.
 - Brett M. responded that it is good that the USCDI is aspirational in terms of classes/elements that are included but, once items are added, they need to be rolled out across the broader community.
 - Wayne responded that HITAC should denote items that are ready now and then provide a list of items that they would like to prioritize for the next version of the USCDI. This would help the standards bodies and the vendors/ecosystem to prepare.
 - Steven suggested that ONC could create a list of items that are under consideration for and should be prioritized for USCDI v3, v4, and beyond.
 - Al Taylor stated that ONC has conversations with HL7 about items that are under consideration prior to publication of the draft USCDI, and this will continue. ONC added several of the data classes/elements included in draft USCDI v2 as aspirational items.
- o Hans submitted several comments, which included:
 - The roadmap HL7 shared will be helpful for the entire community to work more collectively and to prepare for future versions of the USCDI.
 - The term "standards" means vocabularies, and there are differences between the constructs and approaches of FHIR/US Core and C-CDA. The TF and others must find the middle ground for solutions and guidance that are interoperable.
- Clem stated that surveys could quickly be used to determine any remaining gaps in standard, and many of the SDOH elements are already actionable.
 - Steven summarized Sheryl's comments submitted in the chat that the Gravity Project made coding/standards recommendations for the SDOH items they submitted and asked if these were not already sufficient. What additional gaps does HL7 see?
- Brett M. encouraged the TF to continue to be aspirational in its work.
 - Leslie responded that there are not always stakeholders engaged in the standards development process to accelerate aspirational goals, especially for items that affect data underserved populations.
- Wayne commented that HL7 will try to work more closely with the project teams to determine how far they are in their work. Gravity has not published or balloted anything, so it is difficult to see how close they are.
 - TF members shared some updates on Gravity's work with the HL7 presenters, who promised to follow up.

TOPIC: TASKS 2B AND 2C

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, but Steven stated that the TF intends to deliver its recommendations for Tasks 2b and 2c to the HITAC at its June 9, 2021 meeting so that they might inform the updated prioritization schema that ONC plans to publish in

July. The task force's other recommendations will be delivered to HITAC in September. The TF's remaining tasks include:

- Task 2: Evaluate the USCDI expansion process and provide HITAC with recommendations for:
 - o 2a ONDEC submission system improvements
 - 0 2b Evaluation criteria and process used to assign levels to submitted data classes and elements
 - 0 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

Steven shared ONC's submission evaluation criteria that they used to determine the leveling for draft USCDI v2, which was included on slide #6 in the TF's presentation materials. He explained that Hans previously submitted feedback that the "or" should be changed to "and" in the maturity criteria for current standards to be included for Level 2, which would raise the bar for inclusion. It would then read: "Must be represented using terminology standard **and** element of SDO-balloted technical specification." He suggested that this would leave out items that fall into the "aspirational" category and asked for feedback from the ONC team on how to best accelerate change, even when suggested data classes/elements are not fully supported by technical standards.

Steven asked USCDI TF members to craft suggestions around the prioritization criteria to capture the recent discussions held by the TF. He shared a suggestion for the USCDI v3 update cycle, which was included on slide #12 of the TF's presentation, and explained that the new text was shown in red. It stated that if the draft prioritization criteria for USCDI v3 submissions did not meet the criteria that were already defined, they could be prioritized for inclusion if they address an identified priority data exchange need, including equity, data underserved stakeholder groups, or priority use cases, like public health or the pandemic response.

DISCUSSION:

- Hans stated that, in the future, Level 1 could be the "or" level, where aspirational items could be included, and then Level 2 would be the "and" level, where all necessary standards are already in place to support the implementation of the classes/elements if they are recommended for inclusion in the USCDI.
- Grace commented that some items were suggested from the patient perspective that were leveled as Comment or Level 1 and therefore deemed as out-of-scope for the TF to suggest for inclusion in USCDI V2. She asked how concessions could be made to include items that benefit patients and are connected to specific, unforeseen situations (e.g., COVID-19).
 - Steven responded that classes/elements should be ready to be meaningfully exchanged to be included in the USCDI. Some items might be important at the time and deemed as high priorities, so it is necessary for ONC and others to reach a consensus about what items are ready and what is not.
 - Al responded that the TF may make modifications to the evaluation criteria, but changes will add to the standards development and implementation burden. Everyone should consider if items are mature enough to be implemented, so if the recommendations push items forward that are not ready, just to make a statement of support, that does not help anyone.
- Steven described several paths the TF could take in its Task 3 work (recommending updates for the USCDI v3 submission cycle) and asked members to provide feedback. He asked if there should be two classes within recommendations for the USCDI: one where recommendations are fully baked, and another where items are aspirational/added with an asterisk that they are not technically mature/ready? It is too hard for the industry to review all Level 1 items now.
 - 0 Hans agreed with Steven's comments, and that prioritization is needed.
 - Leslie suggested that use cases (especially the pandemic-related items) could change priority levels very quickly. She suggested that the updated categories could be aspirational, public health demand, and then the current Levels of prioritization.

- O In response to a question about the feasibility of creating an aspirational/asterisk category, Al commented that the "asterisk" category (meaning elements that are too complex, not ready, not supported, etc.) could apply to Level 2, as well as Level 1. ONC is under new administration and new guidance, so they can communicate that items are current priorities but that they also need work to be ready for consideration.
- Jim asked if there could be a ranking/prioritization system where the levels were weighted differently, depending on whether they fit one of the three new categories (added in the red text described by Steven earlier).
- Steven explained that Mark Savage previously presented a comprehensive weighting methodology that was developed by a prior ONC workgroup, but it was deemed too complex. He asked if this was a manageable choice, provided that the TF needs to complete a deliverable on a timeline. The asterisk system could be useful for highlighting aspirational items at each level instead of a more complex system. ONC could use it to call out items to the community.
- Steven asked if HL7 is working behind the scenes to determine if they can support the elements ONC has placed in Level 2 with technical standards.
- Clem stated that the ill-defined FHIR resources associated with the SDOH data elements are the reason they might be held back and advocated for the use of surveys to collect SDOH data similar to what North Carolina has used (the <u>Protocol for Responding to and Assessing</u> <u>Patients' Assets, Risks, and Experiences</u> or PRAPARE survey).
- Hans stated that all of the defined criteria have been met for the SDOH elements except for the IGs, which Gravity is working on. They have been balloted but have not been published; they are not ready today, and the amount of time needed to complete them has not been determined.
- Steven asked AI to comment on where HL7's work needs to be on the SDOH data elements (that have not been balloted or published) to make them ready for inclusion in USCDI v2, given the amount of public support that has been expressed. He hopes that the elements would be able to be included in USCDI v2.
 - Al stated that ONC needs to have additional conversations with HL7 around getting the US Core and C-CDA IGs updated in time. They do not need to be fully published by January 2022, but they need to be ready to respond in time for the items to be included in USCDI v2.

Action Items

As their homework, USCDI TF 2021 members were asked to continue 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

Jim Jirjis: Jim Jirjis Here

clemmcdonald: i am hhere [sic] but do not yet have voice acess . [sic] clem



clemmcdonald: now i have it

Sheryl Turney: Sorry had trouble getting in today

Sheryl Turney: I'm on now

Cassandra Hadley: Great, thanks. I have you down

Brett Oliver: Trouble logging on - now on

Cassandra Hadley: Thanks, got you down.

Grace Cordovano: Yes, operative reports were articulated!

Grace Cordovano: As were advance directives and also autopsy reports.

Leslie Kelly Hall: Grace is the autopsy is in the hospital, it may be a pathology report type in place. @ Hans do you know?

Denise Webb: Hello, I had to join late and no operator is coming on line to let me into the meeting. I am on hold

Cassandra Hadley: Hi Denise, we sent a message to the operator

Sheryl Turney: I thought gavity [sic] recommended the following for coding SDOH, Namboodiri, Sreyas Narayan <<u>SreyasNarayan.Namboodiri@legatohealth.com</u>>

Sheryl Turney: sorry Assessments: LOINC Problems/Health Concerns: ICD-10-CM (billing) and SNOMED-CT (clinical) Goals: LOINC Interventions: SNO

Denise Webb: I have joined the audio now

Sheryl Turney: sorry I have to drop for a conflict that I could not change. I put my thoughts on SDOH in the comments. Are we not able to recommend the standards to be used as recommended by the gravity project for SDOH? thank you!

Grace Cordovano: Is there a standards workgroup that specifically focuses on standards development specific to patient unmet needs? Are we seeing an unmet need in standards development that may be necessary to help us collectively expedite implementation of future versions of USCDI?

Abby Sears: Amen and I couldn't agree more. This is what I have been trying to say.

Leslie Kelly Hall: Yes Clem!

Grace Cordovano: #TeamClem

Hans Buitendijk: There is a Patent Empowerment workgroup in HL7.: http://www.hl7.org/Special/committees/patientempowerment/index.cfm.

clemmcdonald: brett I loved your analogy

Grace Cordovano: Thank you Brett and Wayne!

Hans Buitendijk: SDOH is balloted, but not published yet.

Hans Buitendijk: There are vocabulary standards, but structure is not yet baked as there are multiple options being narrowed and nailed down. They are close, but not yet over the finish line.

Jim Jirjis: What about using a weighting system to weight more heavily items that qualify for the top 5 bullets above, but also have the three in red

Jim Jirjis: sorry I had to miss last time

Abby Sears: We were one of the original builders of PREPARE. They now have four different variations on this. Each state is doing it differently. We really have to find a way to move this forward.

Resources

<u>USCDI TF 2021 Website</u> <u>USCDI TF 2021 – April 27, 2021 Meeting Agenda</u> <u>USCDI TF 2021 – April 27, 2021 Meeting Slides</u> <u>USCDI TF 2021 – April 27, 2021 Webpage (for additional resources)</u> <u>HITAC Calendar Webpage</u>

Adjournment

Steven thanked everyone for their work at the current meeting. The USCDI TF 2021 will hold its next meeting on Tuesday, May 4, 2021.

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