# Health Information Technology Advisory Committee

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

## Meeting Notes | May 18, 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 continue 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. The TF continued to work on its Tasks 2a, 2b and 2c recommendations, and TF members discussed the presentations and submitted feedback.

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
11:00 a.m.     Review Draft Recommendations
11:50 a.m.     TF Schedule/Next Meeting
11:55 a.m.     Public Comment
12:00 p.m.     Adjourn

## Call to Order

Mike Berry, 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
John Kilbourne, Department of Veterans Health Affairs
Clem McDonald, National Library of Medicine
Mark Savage, University of California, San Francisco's Center for Digital Health Innovation
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Abby Sears, OCHIN
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Denise Webb, Indiana Hemophilia and Thrombosis Center

## MEMBERS NOT IN ATTENDANCE

Jim Jirjis, HCA Healthcare
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
Brett Oliver, Baptist Health
Sheryl Turney, Anthem, Inc.
Daniel Vreeman, RTI International

## ONC STAFF

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

# General Themes

## TOPIC: REVIEW DRAFT RECOMMENDATIONS

The USCDI TF 2021 focused on Phase 2 of its work. Recommendations from Tasks 2a, 2b and 2c will be presented to the HITAC on June 9, 2021. The TF will work on Task 3 over the summer, which is due and will be presented at the HITAC's September 9, 2021 meeting.

# Key Specific Points of Discussion

## TOPIC: USCDI TF 2021 HOUSEKEEPING

The USCDI TF 2021 co-chairs welcomed members to the meeting, briefly reviewed the agenda, and highlighted the following housekeeping items:

- 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 DRAFT RECOMMENDATIONS

Steven summarized the USCDI TF 2021's previous work on Task 2a and Task 3 and discussed the TF'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 the TF has previously discussed delivering its recommendations for Tasks 2b and 2c to the HITAC at its June 9, 2021, meeting. Based on TF discussions at the previous meeting the TF would like to consider providing recommendations regarding Tasks 2a, 2b and 2c at the June meeting, leaving recommendations regarding Task 3 to be delivered in September. The TF's remaining tasks include:

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

Al and Steven presented the USCDI TF 2021's recommendations in a shared Google document, which members had been invited to review and provide feedback on over the past week. Steven began by

discussing Task 2a recommendations related to the ONC New Data Element and Class (ONDEC) submission systems. Members were invited to discuss draft general recommendations for improving the system, as well as updates to processes related to the submitter details, data classes/elements, use cases, and challenges.

Then, Steven presented the draft Task 2b recommendations, which were related to the evaluation and leveling criteria, and the draft Task 2c recommendations, which dealt with the prioritization criteria. The co-chairs explained that additional wordsmithing would be done on the Task 2b recommendations. TF members submitted feedback and discussed the draft recommendations, and the co-chairs took note of suggestions. Another version of the recommendations will be presented to the TF.

Al explained that ONC has changed the submission deadline for Version 3 of the USCDI (USCDI v3) to the middle of September 2021. The exact date will be announced soon.

Sasha and Hans presented a number of recommendations from an overall EHR/Electronic Health Records Association (EHRA) perspective on the framework to clarify the priority and maturity of data classes/elements in the pipeline for inclusion in future USCDI versions. They focused primarily on the maturity of the data class/element criteria versus the level of priority. They suggested making a clear distinction between prioritization based on need/importance of the data class/element vs. the maturity of the necessary standards and guidance to enable scalable, consistent implementation with minimum ambiguity. Criteria should be organized/categorized accordingly. This would specifically apply to the following criteria:

- Data addressing Equity/Disparities
- Data supporting underserved stakeholder groups
- Data supporting public health use cases
- Data addressing ONC-identified national imperatives

Hans stated that these criteria should inform only the priority for the data class/element, while separately, the maturity is asserted for the data class/elements relative to the technical standards necessary to support them. Regarding the "Meets national imperative" criterion, the Moderate to High technical and standards uplift should be part of the maturity criteria. He stated that they suggested that the TF distinguish between vocabulary and technical (syntax/format) standards. Throughout the process, it must be clear whether there already are published technical standards. A distinction must be made between foundational standards (e.g., HL7 CDA or HL7 FHIR) vs. IGs (e.g., HL7 CDA C-CDA or HL7 FHIR US Core). The latter is most important within the predominant set of technical standards as HL7 foundational standards allow many ways to solve for the same use case. Only IGs will provide the necessary clarity to enable scalable, consistent implementation with minimum ambiguity.

Hans explained the suggestion that all data classes/elements in the newly published USCDI version must have published supporting technical standards and stated that there are effectively four relevant phases to minimum necessary technical standards: does not exist, in development, in ballot, and published. They suggested that the priority would then drive how much effort Is needed to complete it. He stated that the notion of minimum necessary reflects that an existing version may not yet support the data class/element at all or sufficiently for the purpose at hand, so for purposes of this aspect, a minimum necessary technical standard should be considered non-existent. A key rationale for minimum necessary technical standards to be available at the time of USCDI publication, rather than the later SVAP publication or Certification Update publication, is to enable implementers to more quickly support the new SVAP or Certification Update. While this may not be critical to information blocking considerations in general, it is for certified HIT, given that certification requirements must be met before conformance can be claimed.

Hans stated that priority and maturity change as a data class/element evolves over time, so there is a need to differentiate between prioritization and maturity criteria "now" for USCDI v3 candidates to indicate interest/urgency/priority vs. a year from now when v3 is being finalized. Examples of the "now" and "a year from now criteria were provided.

Hans and Sasha suggested that the "Aligned with existing ONC certification and/or CMS initiatives" criterion should be split to allow recognition that a data class/element may be aligned with a CMS initiative but not be included as a certification criterion. This is particularly important for USCDI versions targeted for an SVAP update as a CMS initiative may require a technical standard for a data element which is not yet required for certification. Were the USCDI to include that data class/element with a CMS-specified technical standard 7other than what is required for certified HIT, certified HIT vendors could not adopt that SVAP, as it references a technical standard that is different from and potentially could not be supported simultaneously with the technical standards in the Certification Edition.

Hans suggested that a new USCDI version should not be published without the minimum necessary technical standards having been published by that time. However, a proposed USCDI draft version could include data classes/element for which minimum necessary technical standards are not yet finished to help identify those that, with some reasonable push, can be completed before the next USCDI version is published with the necessary confidence that it is implementable (i.e., tested and exercised in production). The TF should continue to use the term "modest" instead of "expanded" when considering the amount of technical lift required of a vendor/developer in the context of an SVAP cycle.

## DISCUSSION:

- Grace asked to have the phrase "simple language" changed to "plain language" in the first bullet point under the General ONDEC System recommendations.
    - o Mark suggested the following language: "plain language for the general public."
- Steven asked Al to comment on ONC's perspective of the draft TF recommendation to remove the requirement of ONDEC submitters to complete the full Interoperability Standards Advisory (ISA) user registration process.
    - o Al responded that ONC would prefer to investigate the implications of removing the requirements before advancing this as a HITAC recommendation and discussed ONC's desire to be able to document, track, and follow up on submissions to maintain transparency. They need to assess the feasibility of supporting unregistered access.
- Grace suggested adding a glossary of terms relevant to the ONDEC submission process and ONDEC Prep Sheet that would aid submitters. This could empower a wider range of submitters to participate in the process.
    - o TF members discussed the level of specificity/granularity necessary for the glossary.
    - o Grace stated that her initial recommendation was to find a way to lower the barrier to some stakeholder groups (patients, caregivers) that lack specialized knowledge.
    - o Mark emphasized that the main focus should be on making the submission tool easier to use, not necessarily on building out a glossary. Hyperlinks could be used to provide definitions to terms that users might find confusing.
- Mark asked if the recommendation to allow submitters to include patient stories within the Use Case section of the submission could be amended to include giving submitters the ability to link to stories that have already been written up.
    - o Al responded that this is already possible; ONC does not have a requirement around the formatting for use cases. Project pages and other web pages that describe the use case are already allowed.
- In response to an inquiry from Steven that would help the TF shape its recommendations, Al stated that he did not think ONC had changed the level of any of the elements that were submitted.
    - o Steven stated that the TF would keep its recommendation that ONC perform annual or semiannual reviews of all items submitted via ONDEC to validate levels.
    - o Steven explained that Mark suggested that ONC could use the USCDI TF as a sounding board for questions or items that do not fall neatly into a particular category.

- o Leslie explained the recommendation she submitted that ONC would report to the USCDI TF as part of each annual review cycle.
  - o Denise suggested that this report should go to the HITAC, not the TF. Then, the charges would be put forth to the TF as part of the annual chartering process. TF members voiced their agreement.
- Steven asked TF members to comment on the draft recommendations around creating a USCDI dashboard that would show the number of submissions within each level, the date and time since the last review, and other information.
  - o Leslie suggested getting ONC input on what should be included in the dashboard.
- Steven summarized the recommendation that ONDEC should document/display categorizations of each data element/class, based on each criterion, as well as overall. Then, submitters and commenters should be able to provide more specific responses and to help ONC and the public.
  - o Leslie explained that this recommendation would be helpful in situations where there are disagreements as to whether there are supporting standards for submissions and would provide the opportunity for rebuttal.
  - o Hans requested that this view also be captured by data class so that it would be clear which data elements within a class are priorities, which are mature, etc..
- Steven explained how the Task 2c prioritization criteria have been used by ONC in the past and described the TF's recommendations, which separate criteria based on technical maturity (standards, implementation guides [IGs], testing, implementation, use) from those based on non-technical items (equity/disparities, underserved stakeholders, priority use cases). He requested TF member feedback.
  - o Al clarified that ONC gives degrees of priority to items that meet the various levels of priority, and there are not absolute "must" and "need" minimum requirements. The co-chairs discussed how they might update the recommendations.
  - o Leslie explained that the recommendations were created to promote inclusion in the USCDI process for stakeholders and communities that have been marginalized. She discussed a broad range of factors that should be considered by ONC and explained that the recommendation for identifying priority data classes and elements applied to all levels in the ONDEC process (Comment, Level 1, Level 2).  Consistently identifying high priority items would send signals to the industry regarding where to apply focus to promote maturity and readiness for advancement.
  - o Clem warned the TF that safeguards should be put in place to prevent the inclusion of "garbage items" and suggested that some level of priority should be given to elements/classes already being used in HIT systems. Including data that are routinely being collected and/or are automatically generated as these would not require extra work/additional manual collection on the part of systems and users. The TF should not be stingy in terms of including items in the USCDI.
  - o Al responded that the leveling criteria takes into account current use in systems. This aligns with ONC's criterion of minimum implementation burden. "Easy lifts" would be given greater consideration, he explained.
  - o Hans asked about the potential friction between items that are in the USCDI that do not have a minimum level of technical support.
  - o Al responded that there are a minimum number of criteria that must be met for an item to be designated as Level 2 (either represented using clear terminology standards or having an IGs) for consideration for inclusion.
  - o Hans asked ONC to provide clarity around how the proposed updates to the USCDI are/are not aligned with the next Standards Version Advancement Process (SVAP) and the next regulatory update, where the floor is raised. The criteria for each might be different.
  - o Steven responded there is a natural progression from inclusion into USCDI to inclusion in SVAP and then progressing into rulemaking.

o   Al responded that the versioning process for the USCDI is most closely related to the SVAP cycle. ONC will determine if USCDI v2 is appropriate to be considered for SVAP, which will come out in January 2022, and then developers can update their systems and provide the next version to their customers. A proposed rulemaking cycle is coming up, and he described several ways that could be handled.

o   Hans thanked him for the explanation and stated that the industry does not clearly under the criteria, cycles, and process at this time.

o   Al explained that ONC is making an effort to consider the addition of data elements in a version of USCDI with the same level of seriousness as if it were a notice of proposed rulemaking (NPRM). They would like for each USCDI version to be sequentially supported by HIT systems, even though that process is initially voluntary. Any published final USCDI version could be included in the next rule.

o   Steven asked the TF to consider the key issue that USCDI v1 included a number of data classes/elements that were grandfathered in without the specification of minimum technical standards. The TF and ONC must take a position as to whether all new items will require a minimum technical standard going forward, even though there are items currently in the USCDI (v1) that do not meet this requirement. He suggested that the TF owes it to stakeholders to assure that new items recommended for inclusion in a future version are mature enough to support meaningful exchange. He differentiated between putting items into a draft version of the USCDI and a final version of the USCDI. Including an item in a draft version can be used as a signal to the industry to finish maturing items., but he stated that it would be a mistake to include immature items in a final published version

o   Mark commented that, in his work on social determinants of health (SDOH) data, he has seen a range of deadlines for accepting, considering, and approving submissions by coding stewards. The timelines do not always align easily, so discretion is needed.

o   Abby commented on the importance of the rigor of the process but also emphasized that nobody is using this level of rigor in the field. They are making demands on the capture and exchange of data, and they are already using duplicative and manual methods to capture the data they want. She asked the TF to find a balance between the process and the expectations in the field for those that are required to capture the data and would benefit from standardization.

o   Leslie suggested that the TF consider how to flag situations in which the lack of consistent descriptions and standards, combined with the high degree of exchange, are creating chaos. She suggested that a rapid cycle process could be introduced.

o   Abby voiced her support for Leslie's suggestion and discussed the example of systems capturing data regarding "occupation," though it is not yet included in the USCDI. If they are not given tools to organize the chaos in the field (especially for social services and mental health care), data will be produced and reported that cannot be exchanged or used effectively.

o   Sasha stated that Abby's comments are representative of those taking place in the industry around the need to emphasize the prioritization of standards works separately from maturity for inclusion in the USCDI. Sometimes, work needs to happen rapidly, and methods will be in flux until the best, most effective approach is determined. She cautioned that adding an item to the USCDI (leading to the SVAP and certification requirements) can lock the industry into a particular standard prematurely before an  appropriate iterative work cycle is complete.

o   Denise described challenges she has encountered while working with a subspeciality that has significant data needs. She stated that the national organization is not paying attention to the USCDI and is taking actions in the absence of standards to get data entered into their registries, creating burden on providers. She voiced her support of Abby's comments and asked TF members to provide feedback on how to get organizations to encourage the inclusion of registries and education for registries. Leslie supported her comments, noting that COVID-19 highlighted these challenges.

- o  Steven asked TF members if certain items should be added to USCDI, even in the absence of technical maturity. The HITAC and ONC will have to consider this key question.
  - o  Hans suggested that the TF consider the potential for friction and issues with adoption that may arise if items are promoted for inclusion without requisite maturity.
- TF members responded to Hans and Sasha's suggestions, which they provided as members of the EHRA, and asked them to provide clarifications.
  - o  Clem reinforced the notion that new requests should not be created for data elements that are already contained in an included data class and reinforced the need for human judgment over the creation of an even more detailed/granular leveling/prioritization process.
  - o  Steven asked TF members to examine the comments Hans and Sasha provided and to be prepared to discuss new recommendations that will come from their comments at the next meeting.
- Steven summarized the main points made by TF members and several questions raised. In particular, he asked for TF members to comment on whether all items for inclusion in the USCDI must meet technical maturity standards.
  - o  Mark commented that the totality of the circumstances should be considered and balanced. ONC will make the call. If there is a bright line that some items are allowed in while are others are not, though they might be important, it could cause chaos and harm.
  - o  Michelle argued that items should only be included when they meet minimum technical standards, and there should be a separate/adjacent category for items that agencies/the public want items that do not meet technical standards.

## Action Items

As their homework, USCDI TF 2021 members were asked to review the comments Sasha and Hans submitted and the draft TF recommendations. They should be prepared to discuss all recommendations and submit feedback at the next meeting.

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 to the USCDI Task Force meeting.  We will be starting soon.

Hans Buitendijk: Struggling with sound of both channels.  Will drop and be back.

Andy Truscott: Hans: I mute the Adobe Connect channel and just use phone (in case that's helpful)

Hans Buitendijk: The Adobe controls are not showing, making that hard...  Retrying to get back in and get them to work...

Liz Amos: Clem McDonald will be joining late

Hans Buitendijk: I will have to fully reboot to fix the problems at hand.  WIll *[sic]* be back.

Andy Truscott: Excellent Plan.

Leslie Kelly Hall: That need to be "plain" language

Leslie Kelly Hall: We will go over all 2a then go to questions

michelle schreiber: sorry to be late but just to let you know I have joined. thanks.

Mark Savage: Or, "plain language for the general public".

Hans Buitendijk: Back and everything is working as advertised again.

Grace Cordovano, PhD, BCPA: Fantastic suggestions on improvements to the ONDEC system! TF members should push these improvements, when implemented, out through their social media channels and networks.

Clement McDonald: this is clem -- I am  now on line. Had another meeting that collided before

Leslie Kelly Hall: @abby do you want to comment?

Hans Buitendijk: A little higher on the page is where it starts.

Ricky Bloomfield: When SVAP was originally being discussed as part of the NPRM, I recall that one of the primary motivations was to allow advancement of FHIR *version* without requiring a rule update. E.g., the industry could move to a new version of FHIR (such as R5) without needing new rulemaking. This can often happen independently from adding new data elements.

Leslie Kelly Hall: @Ricky, how could this inform our recommendation

Hans Buitendijk: @Ricky: Within F

Leslie Kelly Hall: Placed this draft in the V3 section: Develop a rapid cycle design process for USCDI inclusion and/or standards version advancement to accommodate data classes/elements that are emerging within exchange, where the the [sic] ambiguity and lack of standards can create confusion or harm. (e.g. occupation, SDOH….)

Hans Buitendijk: "FHIR" then ther [sic] is the IG (US Core) as well to consider.

Ricky Bloomfield: Yes, the two will almost always go hand-in-hand.

Hans Buitendijk: That is the only FHIR IG called out to support USCDI.

Abby Sears: Exactly. This is exactly what is happening. The industry has been driven by large hospitals and the mainstream clinical parts of the system.

Hans Buitendijk: I.e., can SVAP include a different IG that was not yet in rule making, thus would not be a next vesion, but a new "standard"?

Hans Buitendijk: Case in point, SDOH is a new IG, built on US Core where in place, but otherwise new and "different".

Ricky Bloomfield: I'd have to go back to look at the language, but I think the *intent* was to advance versions rather than recommend wholesale different IGs. This might meant [sic] that the priority should be to focus on expanding US Core to include new data types (such as SDOH) where that work has been done.

Leslie Kelly Hall: Thanks@ Ricky

Leslie Kelly Hall: Just placed in t V3 to capture @grace, @abby @denise comments. Investigate how registry organizations  can be encouraged and educated on USCDI process and ONC process. Perhaps identify a registry "champion" within ONC to advance registry inclusion.

Leslie Kelly Hall: @Ricky could this in the Evaluation criteria review capture this? Annual review of ONDEC should encourage advancement across leveling.?

Ricky Bloomfield: @Lesley, yes that could be a good approach.

Ricky Bloomfield: Version advancement happens very slowly, though. Every 2-3 years at most.

Ricky Bloomfield: (For major FHIR versions)

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

Leslie Kelly Hall: @Sasha and @Hans, we will review and capture in our grids for discussion next week? There is a lot here. ok @Steven?

Leslie Kelly Hall: Thanks @Ricky I included.

Abby Sears: or how do we create an overall more nimble process

## Resources
USCDI TF 2021 Website
USCDI TF 2021 – May 18, 2021, Meeting Agenda
USCDI TF 2021 – May 18, 2021, Meeting Slides
USCDI TF 2021 – May 18, 2021, Webpage
USCDI TF Meeting Calendar Webpage

## Adjournment
Steven thanked everyone for their work at the current meeting. The USCDI TF 2021 will hold its next meeting on Tuesday, May 25, 2021.

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