Health Information Technology Advisory Committee

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

Meeting Notes | May 11, 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. Michael Lipinski presented an ONC Office of Policy Briefing on electronic health information (EHI). The TF continued to work on Tasks 2b and 2c, and Al Taylor presented an overview of the ONDEC Submission System. 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
10:40 a.m.	ONC Office of Policy Brief on EHI
11:00 a.m.	Tasks 2b and 2c
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 10:30 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, Department of Veterans Health Affairs
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine

Aaron Miri, University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver, Baptist Health
Mark Savage, Savage Consulting
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Abby Sears, OCHIN
Sasha TerMaat, Epic
Sheryl Turney, Anthem, Inc.
Daniel Vreeman, RTI International

MEMBERS NOT IN ATTENDANCE

Andrew Truscott, Accenture
Denise Webb, Indiana Hemophilia and Thrombosis Center

ONC STAFF

Mike Berry, Branch Chief, Policy Coordination, Office of the Policy (ONC); Designated Federal Officer
Michael Lipinski, Director, Regulatory and Policy Affairs Division, Office of the National Coordinator (ONC)
Al Taylor, Medical Informatics Officers, Office of Technology

General Themes

TOPIC: ONC OFFICE OF POLICY BRIEF ON EHI

Michael Lipinski presented a briefing on electronic health information (EHI) on behalf of the ONC Office of Policy.

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. The TF will work on the other Tasks (2a and 3) over the summer, and they are 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. The TF will likely take a short break in meetings before the June presentation to the HITAC while the co-chairs prepare the recommendations and related materials.

TOPIC: ONC OFFICE OF POLICY BRIEF ON EHI

Michael Lipinski presented a briefing on electronic health information (EHI) on behalf of the ONC Office of Policy. He began by introducing himself and described the three divisions of ONC's Office of Policy and their recent work/areas of focus. He explained that he would focus on EHI under the Information Blocking rule and provided the definition of Information Blocking in the final rule. It was included on slide #5 in the presentation. He explained how the interim final rule ONC published moved the compliance date for ONC's information Blocking provisions from November 2, 2020, to April 5, 2021. For the first 18 months (between April 15, 2021,

and October 6, 2022), the information blocking provisions will only apply to EHI identified by the data elements represented in the USCDI Version 1. He reminded TF members that the data elements just need to be represented in the USCDI, and the EHI data itself did not need to meet the terminology standard(s) referenced in USCDI V1. For example, a diagnosis could be coded in ICD-10 as opposed to SNOMED. He discussed the types of providers that might not have used electronic health record (EHR) data before.

Michael described changes and clarifications from the Proposed Rule, which were added due to stakeholder feedback. The final rule EHI definition focused on electronic protected health information (ePHI) included in a designated record set (DRS) and does not expressly include or exclude price information. To the extent that ePHI includes price information and is included in a DRS, it would be considered EHI. He described some of the related guidance, noting that it is located on OCR's website, and stated that if data from notes is used to make decisions regarding individuals, it needs to be part of the designated record. Therefore, it is EHI.

DISCUSSION:

- Steven thanked Michael for the presentation and explained that the question of the role of the USCDI and future version has been discussed several times during recent USCDI TF 2021 meetings. He summarized several related questions and comments that have also been raised and invited Michael to comment on them:
    - The industry has not provided specificity about how access to, exchange of, and use of all EHI will be revised in the future.
    - What are the technical standards? What is the format? A clear definition of what belongs in DRS or not is part of the determination.
    - Providers will be held to these conditions within two years, though they are not well defined, and vendors will not be required to have EHI export capability until the end of 2023.
    - USCDI has been suggested as a potential bridge in which vital data elements that are important to the most critical use cases are defined and specified to support more effective interoperability than might be possible with less well defined data. Providing definitions of the technical standards and clear requirements for data element exchange and use could help alleviate some of the confusion created by a lack of standardization for all EHI.
    - Should the USCDI TF 2021 make recommendations regarding future iterations of the USCDI with these comments in mind as a way to ease the upcoming transition?
- Michael offered several comments in response:
    - He described how Information Blocking is like an umbrella over all providers and other specified actors (including developers, health information networks (HINs), health information exchanges (HIEs)). The HIT certification program (like USCDI, which is required for certification) is a way to get more data to be interoperable.
    - He stated that USCDI has, and will continue to have, value in terms of identifying and standardizing data that are important for exchange. However, it will not have a one-to-one correlation with Information Blocking, due to the broadness of the definition of "provider" in the definition.
    - Many providers are covered actors under Information Blocking but are not incentivized to adopt technologies to be able to use the USCDI. He described various examples of these types of providers.
    - The policy focus is to make data available using certified health IT, and if it cannot, the exchange will be made in a way that is "as agreed upon with the requester." If it is not made available in a standardized way, it should be in a machine-readable format. The market will be allowed to decide how to exchange data, which could be via proprietary means.
- Hans submitted several comments:
    - He acknowledged Michael's comments that the USCDI will not have a one-to-one correlation with Information Blocking, but is USCDI intended to eventually include all of the data in the DRS?

- Is USCDI meant to grow over time to encompass EHI (and DRS), even though all providers might not support everything in it? Will the USCDI eventually work to ease the path so, for those HIT systems that are certified, data are not trapped and information blocking does not occur?

  - Michael responded that entities that are going to use the USCDI as currently identified, particularly products that are certified, are going to be more likely to be able to respond to requests for data. However, from a policy perspective, ONC has not indicated they have a policy goal to expanding the USCDI to ultimately cover what will be included in the DRS. They have focused on the USCDI as clinical data. Michael agreed that meeting the requirements of and being certified to the USCDI is an enabler to providing access, exchange, and use of EHI.
- Steven invited Michael to comment on language in the ONC New Data Element and Class (ONDEC) submission system leveling criteria, which was included on slide #16 of the presentation deck.
  - TF members have raised questions about the language for criteria for use cases/number of stakeholders impacted that would result in a data class or element being designated as Level 2. What, specifically does ONC mean by, "Pertains to ***majority*** of patients, providers, or events…"? Does this mean, "the majority of all health care events/the majority of all patients require this data element" or does it mean, "the majority of applicable events, which may be rare events or occur for only a relatively small number of patients"?
  - Al explained that "majority" refers to the broader stakeholder community, and the majority of all events which would require a particular data element. ONC sees this as a way to maintain focus on what the broader community needs because all systems that are certified must use the entire USCDI.
  - Steven responded that many TF members expressed in previous conversations that this should not be the case because it does not address issues related to equity and the needs of data underserved communities. The TF might consider adding a recommendation around this topic in its next submission to the HITAC.
  - Al stated that the TF may decide to support the current ONC interpretation of the criteria or recommend changes.
  - Mark added that populations on the margins will always remain on the margins unless something is done to advocate for their data needs.
- Al asked Michael to share examples of items in the DRS that would not be considered ePHI.
  - Michael responded that the Designated Record Set (DRS) is everything that is accessible under HIPAA and enforced by HHS' Office of Civil Rights (OCR), so it is much broader than ePHI and goes beyond items that are in electronic format. He discussed how the rule limits EHI to ePHI that is in the DRS and ONC's policy decisions around how they determined who should/should not be covered by Information Blocking.
  - Abby asked if ONC might revisit their decisions around limiting EHI, in light of lessons learned about issues with the flows of public health data during the pandemic. Because the Administration is focusing on equity, limiting the data could be an issue. She stated that transportation, food insecurity, and housing are examples of valuable data and asked if they would be examples of ePHI or EHI. She is concerned that social determinants of health (SDOH) data might not be considered under the auspices of Information Blocking. How can they make sure that vulnerable populations are protected, their data can flow, and that any gaps are bridged?
  - Michael responded that arguments could be made to include this information under either, so it could be ePHI if it is identifiable to the individual. He shared the full definitions of individually identifiable health information and protected health information from HIPAA and explained how these are connected to EHI and ePHI.
  - Leslie highlighted the places where SDOH data could be included, like demographic information and in relation to the identity of the patient and suggested that a recommendation could be made to explicitly encourage the inclusion of SDOH data under the PHI definition. Then, it could flow across definitions, so it could be included or excluded and defined by the user.

- Michael explained that ONC has had a vested interest in this issue for a long time. He explained that he would have to look at the USCDI TF's charge to determine if this recommendation could be made officially.

TOPIC: TASKS 2B AND 2C

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 intends to deliver its recommendations for Tasks 2b and 2c to the HITAC at its June 9, 2021 meeting. The others (Tasks 2a and 3) will 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 presented a walk-through of the necessary steps for using the ONDEC submission system process by sharing screenshots and describing the actions a submitter would take during the process. USCDI TF members were invited to review the ONDEC Prep Sheet, which is located at https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-ONDEC-Submission-Form-Prep-Sheet-Final-2.docx

Al explained that TF members were encouraged to submit input and suggestions for how ONC might improve the ONDEC submission form and Prep Sheet. He highlighted sections of the ONDEC submission form, noting how the Prep Sheet could be used to assist the submitter, and he provided tips on what information was required, what would be kept private (i.e., email addresses for submitters are not published with the submission, but names and organizations are), and how to best submit an element/class. Clarity is key, he emphasized. Sections of the ONDEC form include information about the submitter, the data element (users may submit multiple data elements in a single data class as part of a single submission), use case(s), maturity, challenges, review (ONC can make changes to submissions at this stage), and completion. He described ONC's reasoning behind most of the questions and text boxes in each of the ONDEC sections and how they use responses. Submitters acknowledge within the submission form that they are making a public comment, and they may not edit following the submission. However, they may contact ONC to make updates or edits.

Leslie directed TF members to slides #16 through #20 in the presentation materials and highlighted changes to the language and suggestions that were added following previous TF discussions. These were entered in red text on the slides. Additionally, she shared recommendations for updating the process review of the USCDI and for ONC to provide guidance on priority and maturity leveling/criteria. Also, TF suggestions for visual representation were depicted in an example graphic/table. She asked TF members to provide feedback on these slides to the co-chairs and Mike/Al via email. Co-chairs will incorporate Marks' recent suggestions within the slides and will share them at a future meeting.

DISCUSSION:

- Steven highlighted Al's statement that the section of the ONDEC submission system where the submitter identifies potential challenges does not impact leveling decisions. Steven stated that when he filled out a submission, he felt wary that by identifying too many challenges, he coulda negatively impact the progress of his submission. He asked for Al's statement to be stated explicitly at the top of that page in the online ONDEC and also called out on the Prep Sheet.

- Grace submitted several pieces of feedback:
  - Despite her advanced academic background, she found completing the required fields of the Prep Sheet to be prohibitively difficult without reaching out to someone for help. This is a barrier.
  - Could ONC add a drop-down at the beginning of the ONDEC where the submitter chooses from a list of stakeholder groups as a way of identifying themselves? Then, if a submitter chooses patient or caregiver, they could potentially be required to fill out a simplified/less technical version of the ONDEC questions.
  - Allow for the use case to be captured as or illustrated by a patient issue/narrative/story. This area is not self-explanatory for non-specialists who might like to make a submission.
  - If the submitter submits something that has already been submitted by someone else, is there a mechanism to alert them?
  - Al acknowledged Grace's request for more plain language around the submission questions.
  - ONC is working on an advanced search function for the USCDI to allow for searches of data elements/classes in the USCDI, ONDEC, and the Interoperability Standards Advisory (ISA). It will be live soon. TF members who would like to test it should contact Al.
  - Steven stated that he does not support removing questions from the ONDEC based on the submitter's stakeholder group. Rather, he suggested that some categories/questions within the ONDEC could be made optional for those who self-identify as a patient/patient advocate if having so many required areas is burdensome/confusing to the submitter.
    - Grace responded that the bar should not be lowered for these submitters. She suggested that another field could be added to allow for a submitter to share their personal stories at the point of care instead of requiring a more technical use case. Ken discussed the central question about the purpose of the USCDI and different answers to that question guide its purpose. Is it meant to rubber-stamp elements/classes that have mature standards and industry familiarity? Or should the USCDI TF and ONC work to identify what is missing and what is needed in the USCDI to improve patient care? The ONDEC process seems to be speaking to those who have been engaged in this work for some time, and if the purpose is to go beyond rubber-stamping, the ONDEC questions should be reconsidered. If there is not enough bandwidth to move less mature items forward, that should be explicitly stated. More feedback can also be gathered from the vendor community. Leslie responded that the co-chairs raised some of these topics with ONC and discussed the chicken and egg nature of this process. She mentioned the analogy of using the ONDEC as the "nest" where aspirational items could be nurtured.Ricky echoed Ken's comments and suggested that if there is a desire to expand the diversity of submitters/commenters, the process needs to be examined. As it stands, the process requires an amount of technical knowledge and understanding of the regulatory process that limits who might feel comfortable attempting to provide input. He suggested using a form of crowdsourcing (like a Change.org petition) or a very different kind of process to engage a broader set of stakeholders and enrich the submissions.Mark submitted several comments:He suggested using an interview process with someone at ONC to gather information from submitters who may be less technically adept.

        - He agreed that he experienced many of the same issues Grace encountered when filling out his submission but explained that he was able to use information and guidance provided by various contacts at ONC to complete his submission. He thanked the ONC team but also noted that it would be better not to need assistance with the process.
        - If the submission timeline is to be moved up to September 2021, ONC should share this information with the public as soon as possible to allow submitters to have time to prepare.
        - Some of the TF's feedback would necessitate updates to the form, like removing some of the "required" asterisks.
    - Hans agreed that there should be different methods for different stakeholders to provide input depending on their focus area, expertise, etc. He submitted two suggestions:
        - If the submitter checks the "Yes" box to indicate that a standard is mature, there should be space to include information about what the standard and implementation guide are, if they are under development or not, and other information.
        - Al responded that this area already expands to provide fields to capture this additional information.

Action Items

As their homework, USCDI TF 2021 members were asked to review slides #16 through #20 in the presentation materials and to submit feedback to the co-chairs and Al Taylor.

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 to all, and welcome to the USCDI task force. We will be gettting started soon.

Aaron Miri: For everyone new, Michael Lipinski (ONC) is outstanding and one of the true behind the scenes rockstars @ ONC behind so much progress. Welcome to our group today!

clem mcdonald: today is the board of regensts *[sic]* meeting at NLM. I will be here till about 11 AM than have to return ot the board of regenst *[sic]* meeting -sorry

Hans Buitendijk: Just joined.

Leslie Kelly Hall: No worries Clem, reveiw *[sic]* the slides and add comments back for next week.

Leslie Lenert: HI--this is Leslie Lenert--I am on the call now

Mark Savage: +1 Steven

Sheryl Turney: thank you for coming Mike this was very helpful

Leslie Kelly Hall: Thank you Mike!

Mark Savage: Thanks so much, Mike!

Grace Cordovano, PhD, BCPA: Thank you Mike!

Steven Lane: https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-ONDEC-Submission-Form-Prep-Sheet-Final-2.docx

Steven Lane: Please mute your line when not speaking. Thanks!

Steven Lane: Participants may want to follow along on the Prep Sheet itself. These questions are on Page 4 of the Prep Sheet.

Steven Lane: As part of our Task 2a we are invited to make suggestions regarding these questions, answer fields, and explanatory text (in the Prpe Sheet). Any suggestions to make this data collection process more user friendly, inclusive, equitable would be welcome.

Steven Lane: If identified challenges are indeen *[sic]* NOT used to determine the level for a given data class/element this should be explicitly stated on the Prep Sheet and on the web site.

Steven Lane: Al makes the good point that ONC may edit the submitted data/text before the submission is posted to the USCDI site, typically based on discussion with the submitter.

Hans Buitendijk: On the Maturity questions, it would be very helpful to include references to standards/implementation guides already published, in development, on the ISA, etc. beyond vocabulary standards. They need not be part of the regulatory floor in effect at the time of submission.

Hans Buitendijk: Good suggestion on what is expected to be completed based on submitter category.

Sheryl Turney: if you are able to search and you want to add comments to the submission from your stakeholder group is this allowed?

Al Taylor, ONC: @sheryl YES! we encourage collaboration between potential submitters and commenting on others is a way to do this

Sheryl Turney: thank you

Hans Buitendijk: Agreed with Ken that emerging use cases that are not fully defined yet should be encouraged as well to understand direction..

Al Taylor, ONC: The Level 1 and Comment sections of the USCDI are places to identify data elements that are important but not ready for nationwide exchange. ONC and others could draw greater attention to these elements.

Grace Cordovano, PhD, BCPA: Mark: Sounds like setting up something reminiscent of ONDEC open office hours

Al Taylor, ONC: Also ONC hosts the Interoperability Standards Advisory https://www.healthit.gov/isa/isa-document-table-contents can also identify interoperability needs that might be outside the scope of the current USCDI and ONC certification criteria

Grace Cordovano, PhD, BCPA: The visual representation would be incredibly helpful!

Hans Buitendijk: @Steven, @Leslie: Would you like us to forward to you ahead of the call?

Daniel Vreeman: Great job summarizing the ideas Leslie!

Abby Sears: This is wonderful. Thank you so much for the summarization that you have done.

Mark Savage: Thank you Leslie and Steven for all the work between meetings!

Resources

USCDI TF 2021 Website
USCDI TF 2021 – May 11, 2021, Meeting Agenda
USCDI TF 2021 – May 11, 2021, Meeting Slides
USCDI TF 2021 – May 11, 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 18, 2021, and the Phase 2 meeting schedule was shared in the presentation slides.

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