Health Information Technology Advisory Committee

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

Meeting Notes | June 15, 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 recap Phase 2 of its work and to begin Phase 3. The Interoperability Standards Priorities (ISP) TF co-chairs presented the recommendations their TF transmitted to the National Coordinator, and USCDI TF members discussed the points in the presentations that were relevant to their Phase 3 work.

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.	Recap of June 9, 2021, HITAC Presentation
10:50 a.m.	ISP TF Recommendations on Phase 3
11:00 a.m.	Phase 3 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 10:32 a.m.

Roll Call

MEMBERS IN ATTENDANCE

Steven Lane, Sutter Health, Co-Chair
Leslie Kelly Hall, Engaging Patient Strategy, Co-Chair
Hans Buitendijk, Cerner
Grace Cordovano, Enlightening Results
John Kilbourne, Department of Veterans Health Affairs
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
Mark Savage, Savage Consulting
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Sasha TerMaat, Epic
Sheryl Turney, Anthem, Inc.
Daniel Vreeman, RTI International

Denise Webb, Indiana Hemophilia and Thrombosis Center

MEMBERS NOT IN ATTENDANCE

Ricky Bloomfield, Apple
Ken Kawamoto, University of Utah Health
Jim Jirjis, HCA Healthcare
Aaron Miri, University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver, Baptist Health
Abby Sears, OCHIN
Andrew Truscott, Accenture

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)

PRESENTERS

David McCallie, ISP TF 2021 Co-Chair
Arien Malec, ISP TF Co-Chair

General Themes

TOPIC: RECAP OF HITAC PRESENTATION

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

TOPIC: ISP TF RECOMMENDATIONS ON PHASE 3

The Interoperability Standards Priority Task Force 2021 (ISP TF) co-chairs presented the TF's recommendations onas they relate to the Phase 3 work of the USCDI TF.

TOPIC: PHASE 3 RECOMMENDATIONS

The co-chairs presented an overview of the work schedule for the TF's Phase 3 work.

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 3 of its work, and any breaks in the meeting schedule will be announced.
- Steven explained that the next steps in the work of the USCDI TF 2021 would be on Task 3, which is to recommend ONC priorities for the USCDI version 3 (USCDI v3) submission cycle. This work is due to be completed by September 9. 2021. Al added that more submissions are expected for USCDI v3 following the publication of version 2 of the USCDI (USCDI v2) on July 8, 2021. The USCDI website will be updated at the same time, as well as any updates to the evaluation and prioritization criteria for the v3 cycle. Steven invited ONC to reach out to the TF with any questions or comments as work continues on the final language.

- As part of the USCDI TF 2021's Phase 3 work process, a number of stakeholders will present on high priority topics. The Interoperability Standards Priorities Task Force 2021 (ISP TF) presented its recently completed recommendations that are applicable to the USCDI TF's work.
- The co-chairs of the Centers for Disease Control and Prevention (CDC) and the HITAC's joint Public Health Data Systems Task Force (PHDS TF) will present to the USCDI TF at its next meeting (6/22/2021). Subject matter experts (SME) and stakeholders have been invited to present at future meetings on other topics including health equity/health disparities, work on social determinants of health (SDOH) being done by the Gravity Project, and research and patient-centered outcomes (PCORI).
  - o Leslie placed a call for suggestions for additional topics and SMEs that were not included in the announced upcoming presentations.

TOPIC: RECAP OF HITAC PRESENTATION

The USCDI TF 2021 co-chairs described the presentation they gave to the HITAC at its June 9, 2021, meeting. Phase 2 Recommendations on the USCDI expansion process (Tasks 2a, 2b, and 2c) were presented, and HITAC members did not submit much feedback or criticism. Following the presentation, the HITAC voted to unanimously accept the recommendations. Mike confirmed that the recommendations were transmitted to the National Coordinator for Health IT on June 14, 2021. Steven thanked Mike for his work.

Several attendees shared their key impressions from the presentation to the HITAC. Michelle thanked Steven for the excellent presentation. Arien stated that the USCDI TF's recommendations were met with approval and agreement and explained that a key theme was raised, which has carried through all related standards work; if standards are organized primarily around setting and raising the floor, mechanisms for raising the ceiling may be lacking. The framework presented by the TF will address this critical, long-term policy coordination need. David shared feedback from the perspective of a non-HITAC member and stated that while he agreed that the presentation laid out a well thought out pathway, the USCDI TF may have set too high of a barrier in its efforts to raise the ceiling through its acceptance of the current requirement that to advance to Level 2, a data element/data class must be deployed in four different electronic health record (EHR) systems from four different vendors. This requirement might prevent items from advancing to Level 2 once the majority of use cases have been addressed and added. Steven responded that ONC set that bar, and Al added that ONC had not previously received feedback that this was a barrier. Steven suggested that the USCDI TF could address this topic in its Phase 3 work, so minority use cases would be better supported. Denise thanked David for highlighting this point. Leslie added that the HITAC was very complimentary and thanked TF members for their hard work.

TOPIC: ISP TF RECOMMENDATIONS ON PHASE 3

Steven welcomed Arien Malec and David McCallie, the ISP TF co-chairs, who introduced themselves and presented on the topic of the TF's recently completed recommendations and report to the HITAC.

Arien summarized the connections between the two task forces and added that they would ensure that their recommendations to the HITAC and ONC were aligned. He stated that the work of the USCDI TF as defining the information exchanged in interoperability and the ISP TF as putting together the policy framework for advancing interoperability, including standards and implementation guidances (IGs) associated with vocabulary, content and transport standards that are the mechanisms by which data in the USCDI flows between stakeholders. He described the process by which the ISP TF 2021 gathered topics and prioritized suggested topics within a framework based on several foundational areas.

Arien presented the ISP TF 2021 recommendations in the following areas, which were detailed on slides #7 through #14 in the ISP TF's presentation slide deck. David presented background information. The

recommendations included:

- Foundational Standards – Fast Healthcare Interoperability Resources (FHIR)
  - FHIR Clinical Decision Support (CDS) Hooks or triggering offline workflows via FHIR Subscription
  - FHIR Questionnaires
  - FHIR Consent Directives
- Foundational Standards – Common Data Model
- Foundational Standards – Terminology
- Healthy Equity
- EHR Data Use for Research, Real World Evidence (RWE), RECOVERY-like Trials, Comparative Effectiveness
- Harmonization of Clinical and Administrative Data for Burden Reduction
- Situational Awareness

DISCUSSION:

- Arien highlighted specific areas in the ISP TF 2021 recommendations and transmittal text where the USCDI was specifically called out. The ISP TF presumed that as data elements or data classes are added into the USCDI, the corresponding work will be done to ensure that data classes are incorporated into the IGs associated with interoperability. He described all of the areas in which alignment occurs between the USCDI and the ISP TF's recommendations and the associated standards and IGs.
- Hans Buitendijk emphasized the importance of the ISP TF's 2a-1 and 2a-2 (Common Data Model) recommendations on mapping. He asked if the TF's recommendations around specific terminology standards were consistently presented across all sections of the transmittal letter.
  - Arien responded that the ISP TF made the same recommendations across other sections of the report and listed some of the terminology standards that the ISP TF called out in its recommendations. He thanked Hans for the comment.
- Arien explained that some of the ISP TF's recommendations on terminology standards were controversial, and they are awaiting further commentary from the American Medical Association (AMA) on one recommendation. He provided background information on these recommendations.
  - Clem McDonald stated that the data models in the ISP TF's recommendation referred to research data models, not clinical, and added that only some models support USCDI-like vocabulary standards. When the TF considers models, convergence should happen around those that already are converged on USCDI, like the Observational Medical Outcomes Partnership (OMOP), FHIR, and the National Patient-Centered Clinical Research Network (PCORnet) common data models. PCORnet needs funding to move users. Also, he explained that NCVHS made a more open recommendation to eliminate the boundaries between vocabularies for research, clinical care, and administration.
  - Arien stated that USCDI TF members might have misunderstood the ISP TF's recommendations, which were not calling for the use of one terminology system over another. Rather, they recommended that ONC work with stakeholders to apply the policy framework, which should be in alignment with NCVHS recommendations.
  - Clem cautioned against focusing on one country's model as the standard, and Arien agreed that the recommendation was to work to align across international standards.
- Dan Vreeman thanked the presenters and stated that NCVHS's deliberations on this topic highlighted the idea that one vocabulary per content area/domain/data class is more useful than maintaining mapping and harmonization work between terminology standards. Would the ISP TF consider elevating that idea in its recommendations?

- o Arien responded that Clem discussed this question during the ISP TF's work on its recommendations and cautioned against creating many meta-models that would cross-map between models. Rather, one model is needed for doing research that is cross-mapped to the USCDI. Similarly, they decided that cross-mapping to international terminology standards while allowing multi-regional pooled research will support movement toward their end goal.
- o David commented that these recommendations work toward long-range goals, but they also address real-world problems, like the example of diagnosis not aligning with the problems list, which places a burden on physicians and generates lost information.
- o Arien agreed and explained that the ISP TF called for alignment with the Intersection of Clinical and Administrative Data Task Force's (ICAD TF) recommendations.
- o Leslie stated that there are licensing issues around the coding of vocabularies, which do not require that the data that are passed on are human-readable. When the data move to a consumer-based app, the provider and payer may need to be looped back in to explain the data. She asked how they might address this issue.
- o Arien stated that this issue is connected to licensing rules for terminology, and intellectual property licensing cannot be placed around textual data but can around codes. He stated that the ISP TF's recommendations relative to open terminology are consistent with a call to ensure that all stakeholders in the ecosystem receive usable content, including human-readable text.
- o David stated that there should not be a barrier for a consumer to use a required vocabulary.
- o Leslie stated that not ensuring patient access to the record via the way the data are coded could be a form of information blocking.
- Arien discussed the ISP TF's recommendations related to health equity and provided background information and examples.
- Arien described the ISP TF's recommendations on EHR Data Use for Research, Real World Evidence (RWE), RECOVERY-like Trials, and Comparative Effectiveness. He stated that the research model described in these recommendations is learning health system/pragmatic research/RECOVERY type/comparative effectiveness type model for research, not a model for industry-sponsored clinical research.
  - o David commented that the ISP TF heard testimony from three different research groups (OMOP/OHDSI, FHIR, and PCORnet) that are in the process of working to find the best way to extract data out of FHIR and put it into a more relational model. The three groups indicated that this work is difficult and continues to require funding.
- Arien discussed the ISP TF's recommendations around the Harmonization of Clinical and Administrative Data for Burden Reduction and Situational Awareness and described several related examples for each recommendation.
- Steven thanked Arien and David for their presentation and reminded USCDI TF members that the ISP TF recommendations have been transmitted to the National Coordinator. The USCDI TF does not need to replicate those recommendations that do not relate specifically to the USCDI and should concern itself with opportunities to identify ISP TF ideas/recommendations that should lead to specific USCDI TF Task 3 Recommendations regarding Version 3.
  - o Steven added this recommendation from Mark to the USCDI TF shared Google doc for future discussion: "Clarify that USCDI needs to be consistently reflected across all standards/IGs in play including NCPDP, Bulk FHIR and any other standard referenced in HIT certification."
  - o Steven suggested that there may be an opportunity for the USCDI TF to recommend the addition of brand-new data classes in the USCDI, including ones for Situational Awareness data, administrative data, and data elements within a Research data class.
  - o David suggested that existing data classes could be expanded and explained that the ISP TF heard during testimony on COVID-19 related relief efforts that ventilator settings were not being extracted from the EHR. If this content is missing, it is an inhibition to research.

- o Steven suggested that this item could be submitted as a new suggestion, and Arien stated that it could be added to a subclass of device interoperability. These data are often collected in bespoke device data systems and are not presented in interoperable/patient-centered ways.
  - o Clem commented that there are valuable structured data coming from intensive care, including dialysis setting, pump assist settings, and more, and asked if they could be included.
  - o Arien agreed with Clem's comments and highlighted the need to capture and align data from wearable medical devices, as well.
- Mark voiced his appreciation for the ISP TF's efforts to include information on other federal agencies' efforts and additional use cases/ways in which the same USCDI data is used in different settings. He added several points of feedback to the public chat and asked Arien and David if the USCDI TF should consider additional, priority use cases as part of its work.
  - o Arien stated that the ISP TF made comments that analyte machines should be nationally deployed to support standardization with LOINC codes, as opposed to currently, where there are different, disconnected terminologies. He stated that the ISP TF focused on health equity and learnings from COVID-19 relief efforts, so future considerations will focus on care plans/chronic disease management, portal data aggregation across multiple portals, data sharing between federal and commercial entities, price transparency, and occupation and location of work.
  - o Leslie asked if the ISP TF considered including concerns of disease groups in future considerations., including the incompleteness of cancer patients' records.
  - o Arien stated that this would be added to the ISP TF's priority to address disease management
  - o David suggested that home care could also be an area to track, as it might be mediated through non-EHR mechanisms in the future.

Steven thanked the presenters and invited USCDI TF members to identify data classes and elements or other general concepts that should be included in Phase 3 work. The TF will also discuss David's comments about the number of EHR systems required for inclusion in Level 2 at a future meeting.

TOPIC: PHASE 3 RECOMMENDATIONS

Steven presented the USCDI TF's calendar for work to develop its Phase 3 recommendations, and upcoming scheduled meetings were provided on slide #6 in the presentation deck. Additionally, he explained that a meeting has been proposed for June 29 to focus on reviewing data elements in the USCDI TF's shared Google spreadsheet document. The TF will not meet during the first two weeks of July. The meeting on July 20 will likely focus on health equity and disparities or research if a presentation can be scheduled, and the meeting on July 27 will likely focus on SDOH. The August schedule will remain open to allow for the TF to complete a draft of its recommendations and transmittal letter for presentation to the HITAC at its September 9, 2021, meeting.

Mark inquired if ONC has announced the USCDI v3 final submission dates and if they are moved up to September from October, how this would influence the TF's work. Al stated that these dates have not been announced, but ONC is looking at the final two weeks of September. This information will be announced when ONC releases USCDI v2 in July. Al cautioned that dates are subject to change.

Action Items

USCDI TF 2021 members were asked to review and refine the TF's recommendations on ONC priorities related to future versions of the USCDI. As homework, TF members were asked to:
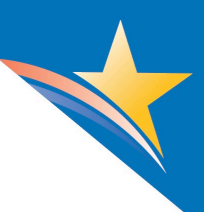
- Review TF members' recommendations document, filtered in Column B for Task #3.
- Edit the TF recommendations document with new Task #3 items with as much information as possible. TF members may also place comments or discussion in existing rows.
- Review recommendations Google document, specifically for Task 3 bullets (USCDI v3 Priorities + Other Considerations), and be prepared to discuss them.
- TF members may make comments on the shared Google recommendations document, but they may not edit or delete any rows.

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! We will be starting soon.

Sheryl Turney: i will have to join 30 minutes late due to a conflict.

Leslie Kelly Hall: Thanks for letting us know!

Hans Buitendijk: Just joined.

David McCallie: did we lose audio, or just me?

Leslie Kelly Hall: I lost it too. had to dial in

Daniel Vreeman: Sounds like a great schedule of discussions!

Leslie Kelly Hall: Welcome David and Arien! Great to see you. I quote both of you often.

Leslie Kelly Hall: @Les Lenert, remember infobutton?

Sheryl Turney: I'm on

Leslie Kelly Hall: Will this construct accomodate *[sic]* patient generated data with questionaires? *[sic]*

Hans Buitendijk: Agreed that USCDI should be mapped not only to FHIR and C-CDA, but also other standards that relate. Not just then HL7 v2, but NCPDP, etc. so USCDI data can consistently through all standards/IGs referenced in Certification at least.

David McCallie: @leslie - I believe that a FHIR questionnaire could be directed to patients, via portal or phone app

Hans Buitendijk: @David: Correct.

David McCallie: I dropped out. Re-dialing

Leslie Kelly Hall: Good news on PGHD Lisa Nelson did some work on CCDA that allowed for patient authors, I hope we can build on this

Mark Savage: Re 2c, would call out FDA's Software Precertification Program in particular for software as a medical device (SaMD) (as well as its opportunity for post-market surveillance and real-world performance measurement).

Steven Lane: Note to the TF: Our goal today is to identify ISPTF ideas/recommendations that should lead to specific USCDI TF Task 3 Recommendations regarding Version 3. The ISP TF recommendations are also transmitted independently to ONC and the National Coordinator, so our TF does not need to replicate those that do not relate specifically to USCDI.

Hans Buitendijk: In that context, emphasizing that USCDI needs to be consistently reflected across all standards/IGs in play as an overall use purpose of USCDI would be helpful to keep on clarifying to the USCDI audiences (even though only FHIR and C-CDA are called out in certification regulations to be used for representing/satisfying support for USCDI).

David McCallie: @hans - yes, for example Bulk FHIR to be specifically referenced

Steven Lane: Added this recommendation to the TF Google doc for future discussion: "Clarify that USCDI needs to be consistently reflected across all standards/IGs in play including NCPDP, Bulk FHIR and any other standard referenced in HIT certification."

Clement McDonald: Want to cheer both Han's and Leslie's comments !!!

Leslie Kelly Hall: Wasn't *[sic]* that because when a specimin *[sic]* is collected at MD office the result is associated with an order number (provider centerd) *[sic]* vs patient demographics?

Hans Buitendijk: @David - Bulk FHIR is a FHIR format directly derived from FHIR, so anything mapped to FHIR then maps to Bulk FHIR where included in that that exchange. So that should be a 2 for 1 opportunity. Growing USCDI to cover full EHI would help ensure that it is clear what Bulk FHIR for EHI Export would cover from a scope perspective.

David McCallie: @hans - I agree that it ought to be easy, but that doesn't mean it will actually happen, unless part of certification tests

Hans Buitendijk: @Leslie - Specimen is attached to the order it was collected for and the patient is was obtained from.

Leslie Kelly Hall: @ Hans but sometimes not connected to EMPI lab result goes to MD to match.

Hans Buitendijk: @David - If the same data expressed as part of Bulk FHIR or an individual FHIR based API is different (other than json vs. ndjson format) we have a major problem on our hands.

Hans Buitendijk: @Leslie - Not sure I follow. Perhaps a side-bar e-mail to understand the flow/relationships better?

Mark Savage: @Steven: Think the point about PGHD and FHIR questionaires *[sic]* warrants consideration (ISP 1a), but also beyond PGHD to RPM, PROs, device data (also ISP 3a, 3b, re my comment earlier about FDA on software as a medical device). ONC roadmap to expand USCDI (2a-2) tracks our recommendation with a comprehensive and concrete deliverable.   And we will have much to contribute across ISP 4!

Leslie Kelly Hall: Agreed @ Mark

Leslie Lenert: FHIR to OMOP is done

Leslie Kelly Hall: Thanks @ Hans

David McCallie: @hans - the vendor's implemention *[sic]* of Bulk FHIR could be different from their implementation of the required API. The mappings could be different, etc. Just calling for those to be aligned and verified

Hans Buitendijk: @David - Agreed that the implementation may not be in sync on whether data is exposed through the individual API or as part of Bulk Data, but when exposed in both it should be synced in format, content, etc.

Steven Lane: @ Mark - Could you draft a specific recommendation for TF consideration?

Mark Savage: @Steven: Yes

Leslie Kelly Hall: Amazing work. So gald *[sic]* you two are champions of this work..

Hans Buitendijk: Bulk Data could serve many different data sets of interest, so an IG against a Buld Data for payer-provider for a particular use case may not need the same data set as exposed in the API, while the other way around would be a interesting discussion to be had.

David McCallie: @hans - avoid gratitous *[sic]* divergence

Leslie Kelly Hall: Human readable exchange should be part of the recommendations when coding is used

Hans Buitendijk: @David - that is frequently THE question around more or less specialized IGs, splitting/combining concepts/classes/resources...

Arien Malec: #TeamLumper

Hans Buitendijk: #TeamConsensusBetweenLumpersAndSplitters

Clement McDonald: I need to step our for a different meetings be gone for about 10 minutes. Apologize

Leslie Kelly Hall: Thanks Clem

Mark Savage: Thank you both so much, Arien and David!

Leslie Kelly Hall: Heroes in the industry! Arien and David!

David McCallie: Thank you!

Grace Cordovano, PhD, BCPA: Thank you for the fantastic presentations!

Resources
USCDI TF 2021 Website
USCDI TF 2021 – June 15, 2021, Meeting Agenda
USCDI TF 2021 – June 15, 2021, Meeting Slides
USCDI TF 2021 – June 15, 2021, Webpage
USCDI TF Meeting Calendar Webpage

Adjournment
Steven thanked everyone for their work at the current meeting. The next meeting of the USCDI TF 2021 will be held between 10:00 a.m. and 11:30 a.m. E.T. on Tuesday, June 22, 2021.

The meeting was adjourned at 11:57 a.m. E.T.