

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

Meeting Notes | June 29, 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 receive public health agency recommendations on ONC USCDI priorities and continue work on its Task 3 recommendations. USCDI TF members continued to discuss TF member recommendations 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 Call10:35 a.m.Past Meeting Notes10:40 a.m.Task 3 Recommendations11:50 a.m.TF Schedule/Next Meeting11:55 a.m.Public Comment12:00 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 John Kilbourne, Department of Veterans Health Affairs Clem McDonald, National Library of Medicine Mark Savage, Savage Consulting Sasha TerMaat, Epic Sheryl Turney, Anthem, Inc. Daniel Vreeman, RTI International Denise Webb, Indiana Hemophilia and Thrombosis Center



MEMBERS NOT IN ATTENDANCE

Jim Jirjis, HCA Healthcare 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 Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS) 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)

General Themes

TOPIC: TASK 3 RECOMMENDATIONS

The co-chairs presented an overview of the TF's Task 3 upcoming work and meeting schedules.

Key Specific Points of Discussion

TOPIC: USCDI TF 2021 HOUSEKEEPING

The USCDI TF 2021 co-chairs, Steven Lane and Leslie Kelly Hall, 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 <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 3 of its work following a short break in the meeting schedule during early July 2021.

TOPIC: PHASE 3 RECOMMENDATIONS

Steven explained that the USCDI TF submitted its Phase 1 and Phase 2 recommendations to the HITAC, and the HITAC voted to transmit them to the National Coordinator for Health IT. Now, the TF will focus on Phase 3, which entails developing recommended ONC priorities for the USCDI Version 3 (USCDI v3) submission cycle. These recommendations will be presented to the HITAC on September 9, 2021. Al Taylor added that USCDI Version 2 (USCDI v2) will likely be published on July 8, along with the guidance for the USCDI v3 submission cycle. Changes to this date will be announced.

Steven presented the working Google documents the USCDI TF 2021 has used to develop its recommendations, including a spreadsheet that contained several data elements and classes for suggestion for inclusion in draft USCDI v3. Steven explained the data element/class submission and leveling process and asked TF members to comment on whether the TF should focus on individual data elements at this point in the process, noting that members could provide input on individual elements during work a future draft version of the USCDI. Leslie voiced her agreement and suggested that the TF provide feedback on guiding principles and high-level clarifications during Phase 3 work. Several TF members agreed, but Mark Savage suggested that TF members should be able to express feedback on gaps without working on the minutia of specific data elements. Steven agreed with this suggestion and explained that the TF would work on its high-level Phase 3 recommendations through the end of the summer

Steven presented the list of data elements/classes and discussed the member recommendations, justifications, and TF discussion captured for each. TF members were invited to provide feedback.

DISCUSSION:

- Steven explained that the Operative Note data element under the Clinical Notes data class was
 mentioned in previous TF member discussions but was not included in USCDI v2. Therefore, it is out-ofscope for the TF currently.
 - Clem and Steven discussed whether the LOINC code for Operative Note was included in USCDI v1. Steven stated that it was not included but stated that TF members or members of the public were welcome to officially submit it for inclusion in USCDI v3 through the ONC New Data Element and Class (ONDEC) Submission System.
 - Leslie stated that the inclusion of this element would address a common area of suppression of data and would benefit patient stakeholders.
 - o Mark added that it is a common use case for supporting cancer patients' post-op second opinions.
 - Al replied that this element may have been submitted in a longer, combined list that the Social Security Administration (SSA) shared.
 - Steven asked if this item was worthy of a formal recommendation to the HITAC, and TF members agreed that a recommendation should be made.
- Steven explained that the Reason for Visit data element under the Encounter Information data class could be captured through the ONDEC system and asked TF members to provide feedback on whether it warrants further TF discussion.
 - Grace asked for clarification about how items from the spreadsheet are entered for consideration in the USCDI process. She suggested that future iterations of the USCDI TF encourage the submission of new elements/classes into ONDEC first, and then all new items are pulled into a spreadsheet for the TF to discuss. The TF will know they are formally submitted.
 - Steven responded that the only way for data elements or classes to be entered for consideration for inclusion in the USCDI is through the ONDEC submission system. Then, items go through the process of leveling, prioritization, and selection, and, later, the USCDI TF may then weigh in on items. He responded that there are 100s of submissions in ONDEC, noting that it might be difficult to review everything. He asked Al to comment on how items might be extracted for future TF review.
 - Al added that this element is in the ONDEC live website. He explained that the ability to extract from ONDEC does not exist but noted that published data elements, which were accepted and given levels, are available in the level tabs in ONDEC. He stated that these tabs would provide current, updated information, while a spreadsheet only shows a snapshot. ONC is working on adding an enhanced search function to ONDEC.
 - Steven stated that the TF should not focus on items at the Comment level or Level 1 in ONDEC at this time but suggested that TF members could add comments on items in ONDEC, especially if they feel the items have been mis-leveled.
- Steven highlighted previous TF discussions about the Autopsy Report data element under the Laboratory data class, noting that it has not been submitted to ONDEC, and asked TF members to provide feedback.
 - Clem explained that the general Clinical Notes category has been accepted and will be advanced in the USCDI. He asked if this data element was included under that category. He discussed the different Operative Notes in LOINC and asked if this item is already required in C-CDA.
 - Leslie responded that Operative Notes is often explicitly not provided or easily available in Open Notes. Often, health systems are resistant to releasing the information.
 - Hans stated that Operative Notes is one of the C-CDA document types that is not required for certification. The TF should examine which items are included and related guidance.

- A with a long list of specific
- Steven stated that there is a submission to USCDI from the SSA with a long list of specific LOINC codes, which is at the Comment level. He suggested that the TF provide a recommendation that ONC revisit the leveling for this item.
- Clem and Steven discussed the Clinical Notes types included in various versions of the USCDI, and Clem suggested that all available Clinical Notes should be included. Steven and Leslie suggested that the TF this part of its recommendations.
- Steven highlighted previous TF discussions about the Blood Type data element under the Laboratory data class, noting that its relevance during COVID-19 relief efforts, and asked TF members to provide feedback.
 - Clem stated that there are many subtypes, and Steven added that these have already been included as Lab Results.
 - Grace asked if there is a way for blood type information to be elevated into the patient record instead of being included as data from a single lab result. This is an example of a test result that is relevant for patients long-term.
 - Al discussed situations in which blood type has greater importance in specific care settings, including pregnancy management. Dashboards can be used to present specific information across care settings, but ONC has not weighed in on the use of dashboards.
 - Steven asked the TF to provide feedback on test results that only need to be done/reported once and should travel with a patient for their lifetime.
 - Clem stated that there is an international standard for key data that should always travel with a patient. Hans shared the web link in the public chat.
 - Leslie suggested that the TF recommend the inclusion of standards that support the access, exchange, and use of this minimum data set.
 - The TF will discuss this item in the future, following a review of the Fast Healthcare Interoperability Resource (FHIR) IPS (International Patient Summary) <u>http://hI7.org/fhir/uv/ips/profiles.html</u>
- Steven highlighted previous TF discussions around the need to include the Advanced Directive data element (along with Do Not Resuscitate Orders, Physician Order for Life-Sustaining Treatment (POLST)/Medical Orders for Life-Sustaining Treatment (MOLST), under the Laboratory data class, noting their relevance during COVID-19 relief efforts. He invited TF members to provide feedback.
 - o Mark suggested that the TF recommend that ONC move quickly to address this item.
 - Clem stated that this is a challenging issue and added that the latest version is needed. He explained that there is no common place to store or find this data.
 - Leslie and Hans explained that significant work has been done through HL7 but also agreed that the USCDI TF should advocate for this issue to be moved forward. Leslie described updates that have been done on the elements. Hans shared links to HL7's documents in the public chat.
- Steven highlighted the Interoperability Standards Advisory Task Force (ISP TF) discussions around including the Location of Work data element along with social determinants of health data (SDOH), which is at the Comment Level, or with Work Information, which is at Level 1. He asked TF members to provide feedback.
 - Mark previously made a comment that the Gravity Project's "employment status" domain is in process. The answers about employment status might or might not capture the "location" of work.
 - o TF members agreed that feedback was already well documented.

- Steven highlighted the recommendations the TF has already documented for the Devices Used (applied) data element and invited TF members to provide additional feedback.
 - Clem stated that the implantable device data are carried by surgery systems and discussed burdens around capturing patient home device data.
 - Leslie stated work has been done for implantable devices but added that it is important to know when recalls happen; implantable device data should be included, as this information is already in Meaningful Use. She discussed public health uses for wearables, referencing information that was relevant during COVID, and stated that the data captured may or may not be useful. More work should be done.
 - Clem and Leslie discussed the topic, with Clem highlighting the related burdens and Leslie advocating for limiting the focus to prescribed devices that are wearable in the home.
 - Hans discussed the need to determine what discrete data could be captured and exchange and challenges around getting information (beyond free text) from electronic lab reporting and on devices used for performing tests.
 - Grace explained that when a patient encounters an issue with an implanted device and calls the customer care line, the first piece of information needed is the model number of the device. Clem suggested linking this information from the surgical suite to the patient's electronic medical record (EMR).
 - Steven stated that the Unique Device Identifier (UDI) has already been included in USCDI v1. At Level 2, there are additional suggested items, like the expiration date, the serial number, the lot number, etc. All the preferred additional data elements have been suggested and submitted. He explained that CMS has already made the suggestions and inquired if any additional recommendations should be made by the TF. Several TF members agreed that this should be an official TF recommendation to the HITAC/ONC.
 - Mark commented that the suggestion to focus on which devices have been prescribed is adequate at this time but also added that the USCDI goes beyond the information that is in the EHR. He discussed several situations in which the ecosystem is broader than what the doctor prescribes.
 - Leslie suggested that the TF recommend that the continued focus should be on devices used by patients and encourage ONC to launch and support a broader review of device interoperability.
 - Clem suggested creating a vocabulary that facilitates searches around consumer device information beyond the UDI. Hans responded that the FDA and manufacturers have encountered challenges around information beyond the UDI (free text, documentation/collection mechanisms, etc.).
- Steven highlighted the Ventilator, Pump, Dialysis Settings, and Data from Wearable Medical Devices data elements under the Unique Device Identifier data class. He asked TF members to provide feedback on the role of the USCDI for defining this data.
 - Clem explained that these settings are Observations generated by ICU systems with associated LOINC codes and added that they are also included in Anesthesia Systems.
 - O Steven added that this will likely be included in the designated record set (DRS) and, therefore, in all electronic health information (EHI). Is asked if this would include EHI maintained in surgical and anesthesia systems, which would then be required by the Information Blocking Rule to be extractable and in a machine-readable format. Al responded that he would check and provide an answer later. Mark responded that it would be in the DRS. Hans stated that, if this is true, it should become a target for the USCDI, and Clem stated that all electronic data should be included.
 - John agreed that this might not be a high priority for a TF recommendation. He stated that it does not seem to fit within the scope of USCDI - not "core" for all systems to be able to exchange.
 - The TF discussed what should be included as "core" data for the USCDI. Is it meant to expand to encompass all EHI? There are settings/systems where some of the data are not necessary or relevant, like small doctors' offices. They discussed how data can create burdens for physicians. The TF will revisit the discussion again.

- Leslie explained the context behind these submissions, most of which were public health/COVID-19 related. She stated that there is a need for specialty or condition-specific data sets, especially for supporting research.
- Clem stated that Medicare requires the collection of detailed dialysis data on a monthly basis, and codes for collection already exist.
- Hans asked if there is agreement on whether settings are part of the definition and added that settings are being modeled for FHIR R5. A different model is being used, and work is in progress.
- Grace suggested including a Tumor Board Notes data element under the Clinical Notes data class. She explained that tumor boards are typically convened for complex, difficult to treat, rare cases. Patients need access to these notes for continuity of care, patient safety, and for patient shared decision making.
 - Steven summarized Grace's suggestion and asked AI to comment on whether this item has been suggested to ONDEC. Also, he added that the SSA recommendations might include this item.
 - The TF agreed that, if it has not been submitted, a stakeholder could suggest and advocate for this particular note type to be made part of USCDI.
 - O Dan confirmed that there is a LOINC code for this item. The link was shared.
 - o Clem suggested that all elements under Clinical Notes be included in the USCDI.
 - Leslie stated that calling this out in USCDI would help patient access. It has been left out of OpenNotes strategies.
- Mark discussed his suggestion to add a Patient-Generated Health data class and advocated that ONC
 encourage submissions for this data class in USCDI v3 to aid development and integration of patientgenerated and patient-reported health data into the digital health ecosystem using consensus standards.
 Such a data class might also integrate or cross-reference some existing data classes and data elements,
 and he listed several. This new data class would support the submission and interoperability of patientreported outcomes, remote monitoring results, and device data.
 - Steven stated that ONC is not interested in supporting the replication of data elements in multiple data classes. Many of the examples Mark provided are already part of the USCDI. He stated that the purpose of a new data class in USCDI would be to hold new data elements that do not already fit elsewhere.
 - o Leslie stated that a C-CDA covers a patient's results but from the perspective of a provider. This suggestion would indicate a new data author for existing standards in the USCDI. She asked how the author/generator of a data element would be added to ONDEC. She briefly discussed the background process for developing this information and emphasized the need to make patient-generated data compatible for exchange with (but separated from) data generated by other actors.
 - Al confirmed Steven's comments and stated that ONC's position has been that the author of data is separate from the data itself. He stated that there are many data that are patient-generated (e.g., symptoms, questionnaire responses, home vital signs) and explained that data elements in the USCDI are designed to be modular/paired.
 - Hans asked suggested that it could be considered a data element with vocabulary, including patient/person and/or caregiver.
 - Steven described how this topic has been more relevant over the past year when patients have shared data during "virtual visits." Should the data be recorded as patient-reported or collected by the provider? Health IT systems have been left to decide, for now.
 - Sasha described distinctions drawn between patient-reported vitals for purposes of quality reporting (in certified health IT systems) and agreed that this likely would not be considered a separate data class in the USCDI. Provenance has not necessarily been a concern for systems, though clinical validity is a concern. She suggested that the TF have a wider conversation about how to handle these types of data in the USCDI.

- Hans stated that systems determine how to manage this data internally, but in terms of interoperability, the data are the same for the most part. The author can be added for the source; FHIR modeling supports multiple author types and keeps data in the same field, regardless of author. He suggested that additional work on data stratification/management in systems is necessary, but this is work for systems, not interoperability.
- Clem commented that the type of author should be distinguished for data to ensure appropriate open write access.
- Leslie explained that work has been done on use cases focusing on patient responses to physician queries. She stated that, through the use of FHIR, this process will likely evolve to be more like a dialogue between patient and provider than a single query.
- Mark discussed longstanding examples of how this is helpful (advanced directives, the HIPAA right to submit a correction/amendment to the record, etc.).
- Dan voiced his support for Hans' comments in support of designating the performer/author/creator of data as a separate attribute. Different measurements for submitters should not be created.
- Steven reminded TF members that USCDI v1 already includes Author, Organization, and Timestamp. He stated that Source and additional provenance items are currently leveled within the USCDI as submissions.
- Hans suggested that the TF consider that Provenance as a data class applies to all other classes in the USCDI. Leslie explained that every author has a certain level of relevance that applies to every piece of data. Hans cautioned that Provence should not be the sole place where the author is indicated.
- o Steven added that Author Role was also submitted, and it has been leveled.
- Mark suggested the use of a roadmap for integrating patient-generated health data at the same level that clinical health data has been integrated.

Action Items

USCDI TF 2021 members were asked to continue 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 Google document for Task #3 bullets (USCDI v3 priorities and 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.
- Review the editable TF members' recommendations document, filtered in Column B for Task #3, for recommendations that should be "advanced" onto the recommendations Google document.

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

Steven welcomed members of the public and encouraged them to submit comments within the chat feature in Adobe and/or by phone during the public comment period.

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

There were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

Mike Berry (ONC: Welcome to the USCDI Task Force meeting. We will be starting soon.

Hans Buitendijk: I'm on.



Sheryl Turney 2: I agree

Denise Webb: I agree with your comments Steven

Grace Cordovano, PhD, BCPA: Agree and a great opportunity to encourage more activity in ONDEC

Daniel Vreeman: Yes, @Grace, that's what I was thinking too. Early identification of gaps will help facilitate coordination/engagement to organize submissions.

Leslie Kelly Hall: Agreed @ Grace and Daniel, we did include this recommendation offering suggestions to promote ONDEC

Grace Cordovano, PhD, BCPA: I will be making the submission for operative note as well as others.

Grace Cordovano, PhD, BCPA: yes

Leslie Kelly Hall: Thanks nice catch

Daniel Vreeman: I don't see the Op Note term in the list submitted by SSA, though there are a lot of others <u>https://www.healthit.gov/isa/taxonomy/term/2846/comment</u>

Leslie Kelly Hall: We can't get to gaps, if we only look at whats there

Leslie Kelly Hall: @Clem or Hans, what is the OP note LOINC code?

Hans Buitendijk: There are about 700+ LOINC codes for various clinical notes/documents.

Daniel Vreeman: Probably best to point to a ValueSet which includes both the generic Op Note term as well as the more specific subtypes: <u>https://loinc.org/LG38755-1/</u>

Leslie Kelly Hall: Thanks @ Dan

Daniel Vreeman: Think the Autopsy Note LOINC term is: https://loinc.org/18743-5/

Hans Buitendijk: For 13 of them they have clearly defined content (minimum, required, etc.) in C-CDA. If we indicate all 700+ (Dan will have the exact number), we need to agree on what is included/expected. given a certain document/note.

Hans Buitendijk: FHIR IPS (International Paitent Access) <u>http://hl7.org/fhir/uv/ips/profiles.html</u> No explicit reference to blood type.

Hans Buitendijk: FHIR IPA (International Paitent Access - DRAFT) <u>https://build.fhir.org/ig/grahamegrieve/ipa-candidate/</u> - Also no explicit reference. But both have lab results / observations thus could include it.

Daniel Vreeman: Early efforts coming out of PACIO project FHIR IG around advance directives: <u>http://build.fhir.org/ig/HL7/pacio-adi/</u>

Denise Webb: I had to drop of for an emergent matter and am dialing back in now.

Hans Buitendijk: Only EHRs have been required for certification to enable documentation of implantable devices. +1 with @Clem that surgical suites have not been the focus to collect and communicate that information so it is not entered downstream, rather at the source.

Hans Buitendijk: When focus is on prescribed, need to look at Device and DeviceRequest in FHIR, while if historical recollection it is DeviceUseStatement (changing to DeviceUsage in FHIR R5).

Hans Buitendijk: Note that device settings in FHIR are not being modeled as Observations. They are currently not clearly in FHIR R4 and is being worked on for FHIR R5.

Steven Lane: https://loinc.org/85231-9/

Hans Buitendijk: @Dan: aren't there 700+ LOINC codes in this space?

Daniel Vreeman: @Hans, for all notes? Yes, there are a lot of LOINC terms. :-)

Hans Buitendijk: @Dan: Have you heard of any initiatives to "profile" each of them to minimum relevant content is understand, or clearly define them as variants of existing C-CDA document types ?

Ricky Bloomfield: This is an ongoing topic of discussion as part of the Argonaut Write IG work right now: https://confluence.hl7.org/pages/viewpage.action?pageld=113672502

Daniel Vreeman: @Hans - no, I haven't heard of this beyond what was happening (did happen) in the CDA IG work.

joe silversmith: I think I may be the only member of the public here today. I am from Allina Health (Minnesota/Wisconsin). No comments/suggestions at this time but always appreciate the robust discussion

Sheryl Turney 2: I agree with Mark on this

Sheryl Turney 2: Thank you to the leads for your great leadership Stephen and Leslie

Resources

USCDI TF 2021 Website USCDI TF 2021 – June 29, 2021, Meeting Agenda USCDI TF 2021 – June 29, 2021, Meeting Slides USCDI TF 2021 – June 29, 2021, Webpage USCDI TF Meeting Calendar Webpage

Adjournment

Steven and Leslie thanked everyone for their work at the current meeting.

Mike reminded TF members that the next meeting of the USCDI TF 2021 will be held on Tuesday, July 20, 2021.

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