Health Information Technology Advisory Committee
Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | March 15, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary
The focus of the Interoperability Standards Workgroup (IS WG) meeting was to continue to work on Charge 1, which included reviewing the new data classes and elements from draft Version 3 of the United States Core Data for Interoperability (draft USCDI v3) and considering data classes and elements in Level 2 that might be appropriate to add to USCDI v3.

There was one public comment submitted verbally, and a robust discussion was held via the chat feature in Zoom Webinar.

Agenda
10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Workgroup Work Plan
10:40 a.m.	Draft USCDI v3 IS WG Recommendations
11:50 a.m.	Remaining Task 1 Meetings
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 10:31 a.m. and welcomed members to the meeting of the IS WG.

Roll Call

MEMBERS IN ATTENDANCE
Steven Lane, Sutter Health, Co-Chair
Arien Malec, Change Healthcare, Co-Chair
Kelly Aldrich, Vanderbilt University School of Nursing
Grace Cordovano, Enlightening Results
Steven (Ike) Eichner, Texas Department of State Health Services
Sanjeev Tandon, Centers of Disease Control and Prevention *(Attending on behalf of Adi Gundlapalli)*
Jim Jirjis, HCA Healthcare
Hung S. Luu, Children's Health
David McCallie, Individual
Clem McDonald, National Library of Medicine
Mark Savage, Savage & Savage LLC
Abby Sears, OCHIN
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Cerner
Thomas Cantilina, Department of Defense
Christina Caraballo, HIMSS
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Kensaku (Ken) Kawamoto, University of Utah Health
Leslie (Les) Lenert, Medical University of South Carolina
Aaron Miri, Baptist Health

ONC STAFF

Mike Berry, Designated Federal Officer
Al Taylor, Medical Informatics Officer
Matthew Rahn, Deputy Director, Standards Division

Key Specific Points of Discussion

TOPIC: OPENING REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven reviewed the agenda for the meeting and invited all attendees to share comments, questions, and feedback in the public chat in Zoom and reminded members of the public that they were welcome to share verbally at 11:55 a.m. during the public comment period. Steven explained that the co-chairs and ONC team leads are working through the many suggestions and items submitted by members into the WG's working Google spreadsheet. As a result of the presentations the WG heard during previous meetings, many new items have been submitted. The list of submissions will be prioritized within the document and will be discussed first. Steven thanked Hans for his work on mapping the new submissions to the C-CDA and HL7 implementation guides (IGs).

TOPIC: WORKGROUP WORK PLAN

Steven highlighted areas of focus, which were detailed in the March 15, 2022, IS WG presentation slides, and reviewed the charges of the IS WG, which included:

- Overarching charge: Review and provide recommendations on the Draft United States Core Data for Interoperability Version 3 (USCDI v3) and other interoperability standards
- Specific charges:
  - Due by April 13, 2022:
    1. Evaluate draft Version 3 of the USCDI and provide HITAC with recommendations for:
       - 1a - New data classes and elements from Draft USCDI v3
       - 1b - Level 2 data classes and elements not included in Draft USCDI v3
  - Due June 16, 2022:
    1. Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

TOPIC: DRAFT USCDI V3 IS WG RECOMMENDATIONS

Steven invited the submitters of specific recommendations to present on the following draft USCDI v3 data classes and elements and asked WG members to share feedback:

- Patient Demographics Data Class / Patient Address Data Element – Metadata tags (normalization, homelessness)
- Patient Demographics (Sex and Gender)
- Health Status (Disability, Functional Status, etc.)
- Patient Demographics (other)

- Medications– Current Medication List (Michelle Schreiber)
- Facility Data (Michelle Schreiber)

DISCUSSION:

- As background information for the **Patient Demographics Data Class / Patient Address Data Element**, Arien explained that the IS WG previously agreed to use the Project US@ ("Project USA") Technical Specification Final Version 1.0 as the content specification for the Address data element in USCDI and that there should be a content metadata flag, indicating whether or not the data was collected in accordance with Project USA standards. He described ways in which the metadata could be used to address implicit biases in health IT and shared edits to the previously approved text of the recommendation to the HITAC, which suggested including the address metadata specifier list so that there is an explicit value for homeless or lack of stable address.
  - Steven invited WG members to share concerns regarding Arien's question, and Mark summarized the background conversations that he and Abby had prior to sharing this recommendation. He explained that because address is not the only element that can be used in patient matching, they would still like the WG to include a recommendation that ONC explore patient matching options that utilize additional data elements. OCHIN is willing to participate in testing those within the next several months.
  - Steven stated that while such a recommendation is outside the scope of the WG charge, such a recommendation could be included with the WG's report to the HITAC.
- Arien shared background information from the Gender Harmony Project's presentation to the WG related to the current USCDI field of **Sex Assigned at Birth**, which is a data element under the **Patient Demographics** data class. He recommended altering the definition and label of the element to indicate that this is Recorded Sex or Gender, as recorded at birth in accordance with the Gender Harmony data model. He explained that this recommendation clarifies the meaning of this term without implying anything beyond the administrative information that was recorded at the time of birth and invited WG members to share feedback.
  - Mark stated that the Gender Harmony Project's recommendations went beyond what was included on a birth certificate for a patient's gender, and Arien responded that the GH recommendations was that this data would have collection and validity dates attached. Mark and Abby noted that they have a broader recommendation that recorded sex or gender goes beyond what is collected at birth, and Arien commented that his recommendation is meant to fix the technical definition of an element that is already in the USCDI.
  - Clem commented that operational considerations should be taken into account, and Steven responded that, as with everything that is included in the USCDI, it does not specify that the data needs to be collected or in what manner. It means that if it is collected operationally and documented, then it is available for and shall be exchanged.
  - Arien added that this is a routinely collected field, so the recommendation is meant to remove ambiguity. Ike suggested to change "recorded" to "observed," and Al explained that this is based on an observation at birth. Ike and Mark noted that a birth certificate could be changed later and suggested updates to the wording. Arien described how this data element differs from the Administrative Sex or Gender data element field.
  - Abby asked about future steps, and Arien explained that his intent was only to clear up the definition of the data element. Arien shared the specific recommendations from the Gender Harmony Project's presentation to the IS WG and noted that this is intended to be a neutral description of recorded or observed sex that has a specific acquisition date and validity period. Ike asked if a technical correction could be made due to a data entry issue, and Al and WG members discussed how the data are collected administratively (as opposed to observationally).
  - WG members discussed the wording of the specific recommendation and reviewed the

Gender Harmony presentation. Al suggested that the scope of the recommendation be updated to read “recording,” instead of “observation.”

- The co-chairs reviewed the four recommendations to update the **Disability Status** data element under the **Health Status** data class, and they explained how prioritizing recommendations around Assessments could affect the WG’s future considerations. The WG is working to ensure that the architecture and structure of the USCDI are logical.
  - Terry O’Malley explained that he submitted the proposed recommendation because there is no clear place in the USCDI currently for structured standardized Assessments. He explained that Assessments could be categorized in several locations and suggested that they be brought together within a single data class.
  - Clem commented that there are thousands of assessments used across healthcare, so it is an important data set to capture. He also commented that there should be some way to call out the most useful ones, but Terry responded that any/all standardized assessments should be included..
  - Mark asked if values that are self-reported and not externally validated should be entered into Patient Demographics, as opposed to Assessments. Steven stated that the WG could handle self-reported data in a number of ways and suggested that all assessments should be located in the same data class; then, a consistent method should be used to identify whether the data was self-reported data or captured by a provider or other care team member for any given assessment.
  - Ike commented that both structured and unstructured data should be included in the framework for documenting assessments. He stated that some general assessments are useful and have good vocabulary standards and/or associated LOINC codes but emphasized that there is also value in the ability to capture and exchange unstructured data to support rare disease use cases and specific assessments prior to the time that associated LOINC codes are developed. He discussed examples of how unstructured data could support the use case of his own disability status and how assessments he completed could be identified as self-reported (or not).
  - Arien agreed that assessments can include those with associated LOINC codes as well as those without, and self-assessments should be included in addition to externally administered assessments. He described how ONC has dealt with the capture of **Disability Status**, as a specific type of Assessment in electronic health record (EHR) workflows and how expectations for clinically relevant assessments are handled in terms of certification and interoperability. He explained that if the recommendation is adopted, future discussions will become simpler. Clem agreed that the self-assessments should be given equal status but that assessments performed using validated instruments should be distinguished from unvalidated.
  - Ike and Arien discussed how **Disability Status** documentation in the EHR could be structured or unstructured. Arien explained how assessments could be captured but added that the method of capture differs from the location of Assessments in the EHR. Ike suggested assessing an individual’s ability and individual health conditions is different than assessing disability.
  - David suggested that the WG should not call out particular assessments and instruments that must be exchanged as part of the USCDI. Listing all possible assessments is not in scope for the WG, but the WG could call out assessments that should be included if collected.
  - Steven summarized the proposal to change the terminology to **Health Status/Assessments**, with the understanding that this would include structured, standardized, validated assessments, with the proposal of listing specific examples that could/should be exchanged within the data class (and specific data elements) when collected. Examples of assessments that were included were brought forward from previous USCDI Task Force work. Mark asked that the identification of self-assessments should clearly be included in the language of the recommendation, and Steven offered to update

the text prior to further review.

- Arien reviewed the recommendation to expand the **Mental Status** and **Functional Status** subtype under the **Health Status/Assessments** data class). The recommendation is that **Mental/Cognitive Status** would be the appropriate title for the data element under the newly renamed data class. Arien stated that it that deals with both mental and cognitive status, has a principal way of being interpreted in the overall category and can be assessed using specific tools. A list of example assessments was included in the recommendation.
  - Al and WG members discussed the wording of the recommendation and updated it for clarity. They determined that it could include a recommended value set, and Al explained that a previous iteration of the WG defined a value set, which is a curated list of examples that have URLs linking to specific LOINC codes that can be used for reference. The current WG could make further suggestions around the value set which could be used to help with certification and adoption. Arien suggested that the WG could point to a specific value set that includes a set of standardized assessments for the purposes of common core interoperability.
  - David asked if listing the set of instruments has an impact on certification, and Al responded that a value set of specific assessments could be used as a reference to guide developers to develop the content through capturing and testing the quoted assessments at a minimum. Al explained how ONC could provide guidance (via a companion guide, USCDI reference documents, test methods, or other mechanisms) via providing examples to developers. Arien stated that the WG is only recommending that there be a value set of validated instruments in common use for capturing mental and/or cognitive status. WG members discussed how the lists would be created, noting that they would have a large impact on interoperability.
  - Mark asked how “Mental Status” relates to the USCDI v3 data element of “Mental Function.” Steven suggested that it was a recommended renaming, and Terry commented that he had referenced the same thing in his recommendation. WG members discussed the wording of this data element across versions of the USCDI, and Clem suggested including the list of alternative names for the same element.
  - In response to a question from Clem, Al explained that the list of LOINC codes were named as a minimum set to serve as examples to aid developers.
- WG members submitted feedback that, in terms of recommendations, the **Disability Status** data element should be treated similarly to the **Mental/Cognitive Status** data element.
  - Steven asked the WG to consider whether this data element should be located within Demographics data class, has some have suggested. Arien suggested that it should be maintained under the Health Status/Assessments data class. He explained that Disability Status is not necessarily permanent and is associated with the patient differently than other demographic information. Steven stated that by capturing the source of the data, the concern that this is patient-reporting data could be addressed.
  - Ike suggested using the term “Condition” instead of “Status” to be less technical and more friendly to the patient. Steven agreed that the way that these terms are perceived by the communities to which they are applicable is important, and Mark summarized previous conversations with the disability advocacy community around these terms. Ike commented that the historical focus of the USCDI has been on use within the medical community and suggested that updating the terms could widen its use to larger communities. As more patients have access to their own data, new, more sensitive terms should be considered to manage patient perception.
  - Al explained that ONC deliberately added Status as a new element in USCDI and described how it differs from Assessment, likening it to the difference between a vital sign and a diagnosis. A status is an important thing to check that may lead to a diagnosis/condition. For **Mental/Cognitive Status**, ONC stated that a structured assessment includes patient reporting and could be guided by a value set or list of examples.

- Mark offered to gain insight into the terms used as homework and suggested that the notion of mobility would resonate with the community. Steven suggested renaming the data element "Ability/Disability Status." Arien and Steven discussed how the WG could consider creating overarching recommendations that would apply to this data class. These will be discussed at a future meeting.

TOPIC: REMAINING TASK 1 MEETINGS

On behalf of CMS, Michelle discussed the following recommendations and justification for their inclusion in USCDI v3 (all of which were leveled by ONC at Level 2, meaning that they are eligible for inclusion):

- Data element **Facility Identifier** in the **Facility Level Data** data class
- Data element **Discharge Medications** in the **Medications** data class
- Data element **Dosage** in the **Medications** data class

She explained that these potential inclusions were supported across government agencies, are well-established, and invited WG members to provide feedback. Steven asked Hans to comment on potential challenges to HL7 in relation to these recommendations.

DISCUSSION:

- Michelle Schreiber reviewed the recommendation she submitted on behalf of CMS that a Facility Identifier data element/group should be added to the Facility Data data class. She stated that the initial recommendation was for a CCN, as this is how most facilities are identified, though they recognize that other identifiers could be added in time.
  - Steven reviewed the following draft recommendation and invited WG members to share feedback: "USCDI v3 include an Organizational Identifier, with combination of Identifier and Assigning Authority, which would need to accommodate both CCN and PTAN; allow multiple identifiers; identifier associated with the encounter; this data should be required if known."
  - Clem asked if the WG would create a formal definition for Facility, and Arien responded that the recommendation is referring to an Organizational Identifier (not Facility).
  - All WG members agreed to accept the recommendation.
- Michelle Schreiber reviewed the recommendations she submitted on behalf of CMS regarding the Discharge Medications and Dosage data elements in the Medications data class. She explained that CMS originally thought that the data elements were standardized enough to be brought forward, CMS has decided to table them until the future following the previous WG discussion.
  - Steven asked if a small task group could be created to determine if there are iterative changes that can be made in order to move these data elements into the USCDI. This could be done following the ISA-related work and could involve presentations from subject matter experts (SMEs).
  - Arien commented that the USCDI has no way of capturing the notion of a medication list that is structured or interpreted in any particular way, and he described the historical context for the lack of more structured items in the USCDI, like the medications list. He stated that this creates issues related to interoperability. Michelle agreed that an advantage of interoperability would include a medication list and agreed that a small workgroup could address this topic. She emphasized the importance of this work.
  - Steven proposed that the ONC Interoperability Standards Workgroup be convened specifically to discuss this topic further after completing its work on USCDI V3 and the ISA. WG members voiced their agreement.

Action Items and Next Steps

IS WG members were asked to continue to capture their thoughts and recommendations between meetings in the two Google documents that will inform the WG's recommendations and streamline the conversations. Members should share a Google email address with ONC's logistics contractor at onc-hitac@accelsolutionsllc.com to be set up with access to the document. Once WG members have gained access, they may input recommendations and/or comments into the appropriate documents:

- IS WG Member recommendations regarding Draft USCDI v3 and Level 2 Data Elements (members have full edit access to this document)
- Draft USCDI v3 data elements sheet for recommendations on changing or removing data elements (charge 1a) (members may add comments but may not add lines), and consider these questions:

IS WG members will be prepared to engage in conversations with presenters to better inform the WG recommendations. WG members may enter comments on this topic into the Google documents to keep track of individual thoughts.

- For homework for the extra March 17, 2022, meeting:
  - Address the following recommendations on the IS WG Draft USCDI v3 Member Recommendations Google document. WG members who are the "recommender" will be prepared to support their recommendations and answer questions.
    - Laboratory (Hung Luu) – Entry # (Column A) 38, 40, 42, 43)
    - Provenance/Author – (Mark Savage) Entry #65
    - Health Status/Health Concern – (Terry O'Malley) – Entry #33
    - Consider renaming Disability Status data element as Disability/Ability Status – Entry # ??
    - Complete review of Health Status (Disability, Functional Status, etc.) – Entry # 26-36The WG will use the Draft v3 Data Elements for IS WG Review Google document as a reference to inform any recommendations that pertain to any Draft USCDI v3 data elements.
  - The deadline for submitting new recommendations on the editable spreadsheet is Friday, March 18, 2022, but WG members were encouraged not to wait until the last minute to share input.
  - The WG will try to work through as much of the spreadsheet as possible over the next three meetings, reserving the March 29, 2022, meeting for recommendations that came in that week, followed by prepping the recommendations transmittal for review and finalization on April 5, 2022. The WG must deliver the recommendations letter to the HITAC co-chairs the week of April 4, 2022.
- Members are invited to consider ideas relevant to the WG's Task 2 charge on the Interoperability Standards Advisory (ISA) Standards, work on which should start in early April 2022, following the completion of the WG's Task 1 recommendations to the HITAC. ISA related topics to consider include:
  - FHIR roadmap, standards from FAST, patient access leveraging QHINs for national access
  - Additional exchange purposes that are contemplated in CURES but not perfectly enabled via initial TEFCA
  - Potential standards/IGs for HIE certification
  - Social Determinants of Health (SDOH) / Gravity data standards
  - Race/Ethnicity vocabulary subsets, e.g., CDC
  - Lab Orders/Results

- SHIELD/LIVD, LIS to EHR/PH SYSTEMS
- Public Health (PH) data standards and potential PH Data Systems Certification
- eCR Standards
- Other ISA topics of interest

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There was one public comment received verbally:

Dr. Michael Rakotz, MD, FAHA, FAAFP: Thank you. My name is Doctor Michael Rakotz, and I have been a family physician for 25 years and the Vice President of Heath Outcomes of the American Medical Association. I want to first thank the Interoperability Standards Workgroup and ONC for their efforts to advance and expand the USCDI. Access to a common standardized set of health data classes and elements will help me to treat and care for patients, ensure that individuals are engaged and empowered with data, and support much-needed information exchange across the healthcare community.

High blood pressure impacts more than 120 million people in the United States. It is the leading modifiable risk factor from preventing death from cardiovascular disease. The accurate measurement and interpretation of blood pressure is vital for diagnosing high blood pressure and assessing effectiveness of treatment. With over 20 years of clinical evidence and guidelines, it is clear that proper estimation of an individual's blood pressure requires multiple blood pressure measurements. In other words, obtaining two or more BP ratings and then averaging them. This is true regardless of whether a patient is in an office setting or measuring their blood pressure at home. Moreover, consistent communication average BP it critical for addressing hypertension nationwide. Including average blood pressure in the USCDI will make it easier for physicians and other health care providers to diagnose high blood pressure and assess BP control more accurately.

Physicians need health IT systems that can exchange and store average BP separate and apart from individual readings. This can help with documentation and enable physicians to use the specific information in their clinical decision-making. The Centers for Disease Control and Prevention and the National Association of Community Health Centers agree with AMA and support a standardized blood pressure data element. Our organizations ask that the Interoperability Standards Workgroup include the Level 2 Average Blood Pressure data element in its recommendations for the inclusion in the USCDI version 3. Thank you.

DISCUSSION:

Steven thanked the commenter and noted that it is officially on the public record, was leveled at Level 2, and is now available for ONC and the WG to consider. Arien added that it is already properly encoded in a LOINC code and described how they could be used to indicate that an average of two or more measurements. Clem discussed how clarity is needed around averaging blood pressure readings from a patient versus diastolic and systolic averages over the mean blood pressure.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Arien Malec: Pull the "To:" dropdown to "Everyone"

Kelly Aldrich: Thanks Arien - Kelly Aldrich joined 🙂

Jim Jirjis: Jirjis joined

Kelly Aldrich: No objection ty

Abby Sears: Thank you everyone. We appreciate this and I think this moves us forward.

Ann Phillips: Hi Arien - there are people who do get new birth certificates issued with a gender transition.

Clem McDonald: i did finally get on the web zoom

David McCallie: Can we eliminate the word “assigned” in the USCDI element name?

David McCallie: Calling out specific assessments for attention is sort of the point of USCDI

Arien Malec: But we don’t call out specific assessments currently. Functional status, disability status, etc. doesn’t point to specific instruments.

Steven Lane: +1 @David

Steven Lane: The USCDI TF 2021 previously recommended lists of specific LOINC-coded assessments as "examples" fitting within specified data elements. We can continue that recommendation. These would not be required, but rather exchanged IF collected.

Steven Lane: Beyond the 10-100 specific coded assessment instruments that might be included as examples, others could also be sent, if available, utilizing these same data elements.

David McCallie: Can someone define what we mean by “assessment” in this context? The entire Hx/PE is an assessment, in that highly focused and in some cases structured questions are being asked and answered

Mark Savage: Functional Status and Mental Function do have LOINC codes in USCDI v3 draft.

David McCallie: Assessment vs Instrument - is that a distinction to make here? The Instrument is a pre-defined structure that “assesses” some particular data need.

Mark Savage: For Disability Status, our presenters recommended the 7 questions, which we capture in our consolidated recommendation on Disability Status, Functional Status, Mental Function.

Arien Malec: @Mark — this is one of the instruments that could and should be used to collect disability status using this recommendation.

Mark Savage: Understood. Just responding to comment above that the data elements do not point to specifics.

Arien Malec: For reference the instrument is the ACS/Washington Group assessment.

David McCallie: @clem - these are more complex than simple list of codes?

David McCallie: @al +1

Arien Malec: @al +2

Steven "Ike" Eichner: I appreciate how some may view disability status as being conceptually different than "disability condition."

David McCallie: But the point of adding a specific code to USCDI is to call out the importance, the “should-ness” of the element. So it makes sense to consider calling out the need to calculate and share the average

Steven "Ike" Eichner: I view "disability condition" as a description/descriptors of the ways, from a functional status, I may be impacted by the disease(s) I have.

My disability stems from the disease I have. There is some variation across the patient population with the disease regarding their disabilities resulting from the disease. Some have no limitations, some are lightly impacted, some are more impacted, and some are near fully or fully immobilized.

Coding schemas like LOINC and SNOMED don't directly reflect the limitations I have and their direct connection to my abilities.

Steven "Ike" Eichner: The disease I have does not describe me.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

IS WG Webpage
IS WG – March 15, 2022 Meeting Webpage
IS WG – March 15, 2022 Meeting Agenda
IS WG – March 15, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steven and Arien thanked everyone for their participation, summarized key achievements from the current meeting, and shared a list of upcoming IS WG meetings.

The meeting was adjourned at 12:01 p.m. E.T.