Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | February 22, 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 workgroup planning, review learnings from the previous Project US@ presentation, and work on Charge 1, which includes reviewing the new data classes and elements included in draft Version 3 of the United States Core Data for Interoperability (draft USCDI v3). TF members discussed the topics and presentation and provided feedback.

There were no public comments submitted verbally, but a robust discussion was held via the chat feature in Zoom Webinar.

Agenda

10:30 a.m.10:35 a.m.Call to Order/Roll CallWorkgroup Work Plan

10:45 a.m. Charges 1a Draft USCDI v3 New Data Classes and Elements

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
Hans Buitendijk, Cerner
Christina Caraballo, HIMSS
Steven (Ike) Eichner, Texas Department of State Health Services
Adi Gundlapalli, Centers of Disease Control and Prevention
Jim Jirjis, HCA Healthcare
David McCallie, Individual
Clem McDonald, National Library of Medicine
Mark Savage, Savage & Savage LLC
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)
Abby Sears, OCHIN

Ram Sriram, National Institute of Standards and Technology

1

MEMBERS NOT IN ATTENDANCE

Thomas Cantilina, Department of Defense Grace Cordovano, Enlightening Results 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 Hung S. Luu, Children's Health Aaron Miri, Baptist Health

ONC STAFF

Mike Berry, Designated Federal Officer Al Taylor, Medical Informatics Officer Carmen Smiley, IT Specialist, Standards Division, Office of Technology, ONC

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 were welcome to share verbally at 11:55 a.m. during the public comment period.

TOPIC: WORKGROUP WORK PLAN

Arien explained that the WG would hold a hearing on Disability Status and Accommodations at the upcoming WG meeting on March 1, 2022, and Steven added that additional participants would likely attend the next meeting. Arien 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:
 - o Due by April 13, 2022:
 - 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
 - o Due June 16, 2022:
 - 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: CHARGE 1 – DRAFT USCDI V3 NEW DATA CLASSES AND ELEMENTS

The IS WG co-chairs reviewed Charges 1a and 1b and invited WG members to submit feedback on Draft USCDI v3 content. They displayed a spreadsheet of comments WG members submitted on Draft USCDI v3, some of which were discussed at previous meetings. They thanked the people who submitted the new classes/elements and invited them to speak about their submissions.

DISCUSSION:

- Arien commented that the WG had yet to add its recommendations based on learnings from the presentation from the Gender Harmony Project. He suggested that the WG could recommend the adoption of the Gender Harmony vocabulary for the Gender Identity data element. The WG needs to determine what to do regarding the Sex Assigned at Birth data element. The Gender Harmony's recommendation is that it should not be included for USCDI v3, so the WG could either follow this, remain silent on the issue, or suggest that the element be included in v3, with the addition of Gender Harmony's comments. Arien offered to draft a recommendation for the WG to review.
 - O David McCallie, Mark Savage, and Arien discussed how the WG should handle comments on data classes and elements that are already in earlier versions of the USCDI. David asked how various potential new data classes should be handled, and Mark and Arien stated that Gender Identity is already a field in the USCDI.
 - Al Taylor commented that Sexual Orientation is also already a data element in the USCDI, and it is separate from the Gender Harmony Project's recommendations. ONC is seeking comments on Gender Identity.
- Arien, Mark, and Abby Sears submitted the following recommendations for the Address data element under the Patient Demographics data class:
 - O Arien discussed his comment, in which he recommended the adoption of Project US@ (pronounced "Project USA") address content standards and the associated American Health Information Management Association (AHIMA) implementation guide (IG) as the applicable content model for Address, with a new additional metadata element indicating the content model used for address information (Non-normalized / pre-US@, and US@/AHIMA IG version(s)).
 - Clem asked how high of a lift this recommendation would be, given the fact that there might be some concern about doing this all at once.
 - Carmen Smiley commented that Project US@ does not dictate how data holders, including providers or developers, should handle historical data. The structure, as it exists, is inclusive and leaves room for new data to be collected consistent with the standard and shared. She explained that this recommendation was created as a result of feedback from health IT developers. She explained that Project US@ made its recommendations because there was no current Address content model.
 - Arien commented that the recommendation was structured in such a way to allow for previously collected address information to not have to be reformatted/normalized but to add metadata tags to alert actors who receive and process the data that it has/has not been normalized to the US@ standard.
 - Ike Eichner stated that changing the normalized data would still force the hand of
 the actor to modify/use an API to update it for patient matching. Clem and Arien
 commented that people are matching against data that has not been normalized.
 Ike stated that encouraging normalization is not a bad thing, but it does create a
 heavy lift. Ike suggested that this recommendation likely applies to public health or
 investment in infrastructure in the same space as developing Project US@ and
 investing in that technology upgrade.
 - Arien suggested that the WG could either include a recommendation to ONC to sponsor HHS or the US Post Office to stand up a Project US@ service for the nation, or the WG can include this as a part oftheir ISA-related work. He stated that the USCDI is a content (not an interoperability) specification model.
 - O Abby and Mark discussed their recommendations and explained that the change to a standard would be good, but they wanted to create a pathway to reduce the health equity divide, specifically as relates to individuals without a stable address. The recommendations included:
 - To adopt the Project US@ approach to standardizing current and prior address, with the addition that the terminology and exchange standards should also include an explicit value for homeless or lack of stable address.

- That ONC advances a parallel process with a definitive timeline and deliverables testing multiple options and combinations of distinctive identifiers that OCHIN offers to help test within six months.
- In response to WG member questions, Mark added that adding "lack of a stable address" would be a useful placeholder that tries to avoid embedding structural issues, but he also invited WG members to comment. He stated that it differs from addresses with short-term expiries and from the Housing Instability data element. Carmen commented that a metadata element exists in Project US@ that indicates that a patient is known to be homeless in the specification under the optional metadata fields (not all systems will collect, or it is unknown). WG members discussed how this indicator could be used, and Carmen stated that it would be accompanied by provenance data.
- Abby and Mark will review the content model to ensure that it meets the concerns
 that they raised. Carmen offered to share the document. Arien asked if USCDI lists
 discrete fields and described differences between a content model, including
 relevant metadata for tagging, the ability to add a field as "Unavailable," and
 structured data/semantics, versus what he described as the "a bag of fields" model.
- O Al described ONC's goals that center around adding structure around addresses leveraging the work of the Project US@ initiative. He described how addresses would be represented.
- O David asked about how encoding for this data would be handled and if USCDI would specify the encoding. Should all relevant metadata fields be listed at the USCDI level? If so, he recommended adding them to the WG's recommendations. Arien and Clem discussed how to broaden the current definition of an address via the recommendations. Arien suggested that a high-level content standard would be applied (the USCDI v1 and v2 models), in addition to the AHIMA model.
- O Steven highlighted a comment from the public chat that asked if the Project US@ metadata approach would help with patient matching if it is not part of the address field. Carmen responded that she added a follow-up to the question in the public chat and explained that structuring data, such as "Homeless," helps to avoid variation in descriptive text.
- O Arien described how address is a set of free text fields that are labeled in a certain way, but if the WG were to recommend the Project US@ specifications, it adds structure to the content included in certain fields via associated metadata. Clem suggested that this would only help patient matching, not hinder it.
- o IS WG members agreed to accept Arien's suggested recommendation, pending some light wordsmithing to add the word "standard" after content model.

- In response to David's question, Steven stated that Abby's second recommendation is likely outside of the WG's remit. Abby cautioned against separating the recommendation out, even if it is outside the WG's charge. Carmen explained that the pilot that Project US@ is working on in 2022 will measure the effect of the specification and the API on approved patient matching using algorithmic tests based on unstandardized versus standardized data. She agreed that it was a good suggestion, but it will not be part of Project US@'s next phases of work. Abby explained how the current pilot program only tests matching within organizations. Clem discussed challenges around gathering race and ethnicity data from patients in the hospital setting. Abby agreed that asking these guestions can be challenging but emphasized the need to try to collect this data and to ensure that it is accurate. Jim commented that newer patient-facing apps make the collection of this data easier and possibly less challenging for patients. The USCDI should be ready with data and associated metadata elements to appropriately collect and support this data. David asked about other patient identifiers that could be used for patient matching, but Carmen stated that Project US@'s scope only includes patient addresses. David suggested that Abby's recommendation could be broadened to include persons who do not have a stable address/one that fits into the USCDI metadata to better support patient matching. WG members discussed the best data elements, including address information, that could be used for patient matching and agreed that matching algorithms can and should be improved without magnifying health equity issues.
- O Arien explained how the "bag of fields" model has an implicit bias and suggested moving to the Project US@ content so as to be more explicit. He suggested that OCHIN could help with this work, and Ike agreed that OCHIN or other agencies/organizations could help. He asked about a roadmap with goals and available resources listed. During offline work, WG members will draft a specific recommendation to address these core issues.
- Clem submitted a comment on the Assessment and Plan of Treatment data class and element that LOINC should be an applicable standard and/or provide a sample list in USCDI v3. Clem discussed the use case of providing a glucose sample.
 - O David stated that forcing too much structure on broad categories that are complex/fluid will create problems, and he described how the WG should allow for passing contextual information that summarizes the sense of the plan, even if it is not, in fact, fully encoded. He and Clem discussed how the USCDI should allow for highly structured assessments (depending on use case) and more unstructured assessments that could get passed under the Notes element. Al explained how the Assessment and Plan of Treatment are two parts, with a structure that stems from a legacy data element, and different information is captured that is more or less specific/structured. He explained that the intent is to leave this more open-ended to allow for a variety of data to be entered. David agreed that open-ended/unstructured data has clinical value, even if it is not machine-readable.
 - Steven thanked Clem for his previous work on identifying items from LOINC that should be listed as examples for use within specified USCDI data elements and asked if the WG would like to specify some/all of these LOINC codes. Clem commented that some of this information is included as part of a discharge note. Assessments are usually the more structured part, so Steven asked WG members to comment on whether there should be an Assessments data element to capture the structured data. David responded that some of this information could be listed under the Observations or Lab Results data elements. Hans explained how a system could encode the distinction between structured/machine-readable or unstructured data. The WG discussed if it should recommend a list of structured assessments that could be entered in this field, and AI explained that ONC has already defined value sets and lists of samples or examples for various Clinical Tests. WG members and Al discussed how more structured information could be entered, either as a different data element, like Clinical Tests or Social Determinants of Health (SDOH) Assessments, and Arien suggested that lumping these items together seems unprincipled. Could these items be decoupled into different elements/classes? Have SDOH elements received special treatment?

- O Clem described how nursing homes use these items. Arien summarized the conversation by stating that structured data should be associated with Assessments and paired with a LOINC code. Al described the use of these items in post-acute care settings and how their data requirements led to the current structure of the Health Status data class. David explained that the medication list, which is part of the plan of treatment, is captured elsewhere, so this field should be allowed to be flexible to capture things that do not fit elsewhere. Kelly described her experiences as a nurse and explained how nurses need to document their evaluation assessments and interventions beyond what is covered in LOINC and beyond the information captured by physicians. This will allow for better care coordination.
- Steven stated that the key question is whether to go deeper and to be more specific within this data element and data class. Or should it be left as it is, and then should the WG focus on adding more specificity within Clinical Tests or another class/element. Arien asked for volunteers to craft a more structured recommendation that could include an Assessments Class with specific examples of component LOINC items similar to how ONC has specified the Clinical Tests class. Kelly agreed and offered to help while emphasizing the need to better support the use of more advanced analytics that could help with structured data analysis. Ike offered to help and described his relevant experiences with administering assessments.
- O David asked how and when the USCDI applies to data, and Arien responded that the USCDI is the underlying content model to which interoperability is specified. He described how the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) and Consolidated-Clinical Document Architecture (C-CDA) are mapped back to the USCDI. WG members stated that the model is not specified in the electronic health record (EHR). Al stated that any API or other access via document types would require querying the data classes in the USCDI.
- The WG agreed to draft some recommendations around how to rearrange these classes and elements and discussed how previous work on Clinical Tests could be considered. Steven captured discussion points and stated that a recommendation could suggest adding specificity to existing data classes and elements.
- Clem submitted a comment on the Care Team Members data class and Care Team Member Identifier data element that the codes should be specified in USCDI v3. Currently, there is no code that covers all the possible members. Codes from the applicable code set should be used, as most caregivers have already been associated with them
 - O Al stated that ONC had originally considered adding a specific identifier, like the national provider identifier (NPI) or the DEA number, but these usually only apply to credentialed providers. A broader group of care team members is involved, so ONC decided that they would not require the capture of Care Team Member Identifier in USCDI v2.
 - O Clem reiterated that if applicable codes exist, they should be captured and exchanged. Al agreed and added that a business identifier or a unique nursing identifier could also be captured here if this item is not specified.

Steven and Al discussed the possible WG recommendation around the addition of a code set item (within Care Team Member Identifiers) so that if an identifier is included, the type of identifier could be specified. Al offered to check the companion guide to determine what ONC specified. Hans asked about the level of granularity for this change, as a more detailed data model has already been captured in the standards. Adding an additional Code System data element might be unnecessary, though the USCDI could indicate that there is a minimum set of codes that should be captured, if possible. Kelly commented that any existing standards should be incorporated to allow for discrete analytical data to be captured. Providers should be able to analyze the impact of their interventions and care on patient care outcomes. David cautioned that a nationally scoped global identifier for everyone involved in a patient's care would be useful but that the lift to get there is heavy. He suggested that locally specified identifiers should be acceptable, while globally specified identifiers could be included when available. Clem voiced his agreement. They determined that locally specified identifiers could also include email addresses, phone numbers, or something that identifies family members who are involved with care.

Action Items and Next Steps

IS WG members will be asked to capture their thoughts and recommendations between meetings in 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 provisioned with access to the document. Once WG members have gained access, they may input recommendations and 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 March 1, 2022, meeting:
 - O The WG will host a series of presentations by subject matter experts (SMEs) at this meeting, and they will present on the entire new Health Status data class, including the four new data elements Disability Status, Functional Status, Mental Function, and Pregnancy Status. WG members will review this class and these elements and be prepared to discuss with the presenters.
 - o The shared WG Google documents are available for WG members' comments and edits.
 - All WG members are invited to support Hans in the mapping of Draft USCDI v3 elements to CDA and FHIR. Please consider helping with this important research if you are more familiar with FHIR and C-CDA IGs.
- Members are invited to consider more ideas on the WG's Task 2 work on the Interoperability Standards Advisory (ISA) Standards, 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
 - o TEFCA standards enablement
 - o 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
- o Lab Orders/Results
- SHIELD/LIVD, LIS to EHR/PH SYSTEMS
- o Public Health (PH) data standards and potential PH Data Systems Certification
- o eCR Standards
- o Other ISA topics of interest

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane:

https://docs.google.com/spreadsheets/d/1u2j2zeTbkquuAnBvh4HfTSA6q3EHNTYv/edit#gid=1237705187

Jim Jirjis: Jim Jirjis joined

Carmen Smiley: Note that the Project US@ Technical Specification and Companion Guide does not dictate how providers or developers handle historical data.

David McCallie: I think we'd like to see the USCDI as a forcing function to improve address handling, right?

Hans Buitendijk: TEF would require conversion to US@ as part of the patient discovery flow.

Carmen Smiley: Note that Project US@ scope is limited to patient address data only. Thank you

Carmen Smiley: Also note that the Technical Specification does include a metadata element for Homeless patients

Christina Caraballo: I really like Mark and Abby's recommendation. Is there a reason it is not already in Project US@?

Carmen Smiley: Project US@ Technical Specification and Companion Guide can be accessed here: https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153

Carmen Smiley: Excellent point, Adi - and Project US@ supports all of these scenarios

Mark Savage: Would the Project US@ metadata approach help with patient matching if it's not part of the address field?

Carmen Smiley: For example, homeless shelters should conform to the business address format in the Specification

Carmen Smiley: Regarding the metadata, developers often face challenges when text like "HOMELESS" is included in an address field, and so we added the metadata schema to assist in matching efforts

Arien Malec: We have the computer scientists talking to the social/biological scientists and it's fun.

Abby Sears: I think this makes sense.

Carmen Smiley: We also have metadata fields for things like military address, temporary addresses, multi-unit or shared housing, etc.

Mark Savage: As I recall, current pilot is to test WITHIN org only, not among orgs.

Arien Malec: My view rn is that being explicit about the unhoused or temporary housing/multiple households in the same location, US@ advances equity.

Carmen Smiley: Mark is correct - we are testing within organizations

Arien Malec: Our "bag of fields" representation has implicit bias and we are reducing bias by going to a more structured representation.

Mark Savage: That's my thinking, Arien--structured element in address field.

Jim Jirjis: Can you guys hear me?

Mark Savage: Yes @Jim

Hans Buitendijk: We do need to recognize though what is information/data about the address to be matchable, vs. what is about the person.

Abby Sears: The issue for me is that we really need to fund additional work around this.

Hans Buitendijk: Allocating data about the person to the address further complicates the necessary ability to enhance on the analytics.

David McCallie: Even a bag of fields can capture structure, if you put the implicit structure into the field names. We want the content to include the metadata, regards of the encoding

Arien Malec: Agree @Hans — getting better about address advances the cause for person matching, but also need to have a similar content model about name, and other demographic information.

Hans Buitendijk: Including on the relationship between a person and an address vs. what is about the person regardless of address.

Mark Savage: It helps me to differentiate the data element and the use case. I think a structured value for "homeless"/"lack of stable address" helps both--appropriate detail for address data element, helps with patient matching (both affirmatively and avoiding errors), and helps avoid bias in the algorithms for patient matching.

Steve "Ike" Eichner: This conversation links directly to disability status, which as described is more functional status than anything else

Steve "Ike" Eichner: There may very well be a need for an assessment class

Arien Malec: As a draft recommendation, we deprecate Assessment and Plan of Treatment, and label "Clinical Tests" to "Clinical Tests and Assessments"

Steve "Ike" Eichner: Arien: Would that include assessments completed by a patient at the request of a clinician?

Arien Malec: Current defn [sic] says "Includes non-imaging and non-laboratory tests performed on a patient that results in structured or unstructured (narrative) findings specific to the patient, such as electrocardiogram (ECG), visual acuity exam, macular exam, or graded exercise testing (GXT), to facilitate the diagnosis and management of conditions."

Steve "Ike" Eichner: such as a disease-specific functional assessmet? [sic]

Mark Savage: David's question implies two separate approaches to the data, an internal and an external/interoperable approach?

Arien Malec: We could include "performed with respect to the patient by clinicians or self-assessed" rather than "performed on" which has odd paternalistic connotations as well.

Steve "Ike" Eichner: Is there a need for a class for patient-generated data?

Steve "Ike" Eichner: or patient-reported data?

Steve "Ike" Eichner: THe later is probably more acurae. [sic]

Steve "Ike" Eichner: accurate..

Michelle Schreiber: Agree we likely need a class for patient reported data. This will have implications such as patient downloadable information (glucometers, etc.), as well as patient survey information.

Mark Savage: Think some data elements are patient-generated, and they are scattered among data classes.

Arien Malec: My humble suggestion is that we want assessments to be assessments, but we should contemplate that assessments may be performed by physician, nurse, PT/OT, dietician, pharmacist or by the patient.

Hans Buitendijk: Is the question that we need to identify minimum required (where available) identifier types, or that for an identifier one must capture the type of identifier?

Steve "Ike" Eichner: On care team identification [sic] What should happen with non-credentialed providers, including family members performing specific roles?

Christina Caraballo: Building on Abby's comment: Alliance for Nursing Informatics recommends National Council of State Boards of Nursing (NCSBN) ID

Steve "Ike" Eichner: Having an ID if it is available would be helpful. Maybe a two-dimensional coding scheme-providing organization and individual ID.

David McCallie: I think these identifiers should be locally-scoped and not global. It might be as simple as a phone number for a family member, for example

Hans Buitendijk: The standards that are applicable already have the ability to type identifiers. So this is more about which identifier types are minimally required to be able to capture for care team members.

Steve "Ike" Eichner: The modifier needed for a local identifier is a unique identifier for the issuing entity. This could be an existing OID.

Mark Savage: Does David's comment apply way to internal exchange but not so much for sharing information among organizations, e.g. ACOs or longitudinal shared care planning?

Mark Savage: *apply mostly

Steve "Ike" Eichner: Mark: I think my comment helps address inter-organization issues with IDs.

Hans Buitendijk: Agreed with @Steve(lke) that the identifier need not be unique as long as in combination of the issuing authority/organization and possibly type it is unique.

Hans Buitendijk: But everybody then better be able to hold on to the issuer and type as well.

Kelly Aldrich: @Hans that depends on the question of value equation or output of the system needs (research, care coordination)

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

<u>IS WG Webpage</u> <u>IS WG – February 22, 2022 Meeting Webpage</u> IS WG – February 22, 2022 Meeting Agenda IS WG – February 22, 2022 Meeting Slides HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steven and Arien thanked everyone for their participation and shared a list of upcoming IS WG meetings. The co-chairs will review the list of comments submitted by WG members to develop a prioritized list of focus areas to best use the amount of time available.

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