Health Information Technology Advisory Committee

Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | February 1, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) was to review the workgroup process, continue workgroup planning, and to begin work on Charge 1a, 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). Workgroup members discussed the topics and provided feedback.

There were no public comments submitted by phone, but several comments were submitted via the chat feature in Zoom Webinar.

Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	USCDI Process Review
10:55 a.m.	Workgroup Work Planning
11:05 a.m.	Charge 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
Grace Cordovano, Enlightening Results
Steven (Ike) Eichner, Texas Department of State Health Services
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Adi Gundlapalli, Centers of Disease Control and Prevention
Jim Jirjis, HCA Healthcare
Kensaku (Ken) Kawamoto, University of Utah Health
Hung S. Luu, Children's Health
David McCallie, Individual
Clem McDonald, National Library of Medicine

Mark Savage, Savage & Savage LLC
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)
John Garguilo , National Institute of Standards and Technology (attending in place of Ram Sriram)

MEMBERS NOT IN ATTENDANCE

Thomas Cantilina, Department of Defense
Leslie (Les) Lenert, Medical University of South Carolina
Aaron Miri, Baptist Health
Abby Sears, OCHIN

ONC STAFF

Mike Berry, Designated Federal Officer
Al Taylor, Medical Informatics Officer, Office of Technology

Key Specific Points of Discussion

TOPIC: OPENING REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed members and invited members who were not present at the previous meeting to introduce themselves.

- Kensaku Kawamoto is the Associate Chief Medical Information Officer, University of Utah Health, and Associate Professor, University of Utah Department of Biomedical Informatics.

Steven reviewed the agenda for the meeting and welcomed members of the public. He invited everyone 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.

TOPIC: USCDI PROCESS REVIEW

Arien welcomed Al Taylor, who presented an overview of the United States Core Data for Interoperability (USCDI) Process Review. Before Al started, Arien clarified a few related items. He explained that ONC has a parallel initiative, USCDI+, and work is underway on draft Version 3 of the USCDI (USCDI v3). These are all separate initiatives. He described the ONC Standards Version Advancement Process (SVAP), which is used to advance standards, and it meshes with the certification process. A team is engaged to identify how the SVAP will work with the certification process.

Al described what USCDI Version 1 (adopted as a new standard in the ONC Cures Act Final Rule of 2020) is and discussed why it matters. This information was detailed on slide #6 in the presentation materials. He presented the USCDI Core Principles:

- The USCDI comprises a core set of structured and unstructured data needed to support patient care and facilitate patient access using health IT.
- Establishes a consistent baseline of harmonized data elements that can be broadly reused across use cases, including those outside of patient care and patient access.
- Expands over time via predictable, transparent, and collaborative public process, weighing both anticipated benefits and industry-wide impacts.

Al described the connections between the USCDI, electronic health information (EHI), and Information Blocking, which were highlighted in a timeline depicting the certification process and Information Blocking from 2020 through 2023 (slides #9-11). He displayed a timeline of the USCDI Version Update Process, and he explained the interplay between the key events in the USCDI submission and review periods and the SVAP processes from 2020 to 2022 (slide #12). He stated that the SVAP allows health IT developers in the ONC Health IT Certification Program to voluntarily update their products to include National Coordinator-approved, newer versions standards. The SVAP is limited to standards adopted in specific certification criteria, and he explained ONC's public comment process, and the adjustments made to the SVAP timeline (slides #13 and #14) to accommodate the lag between the USCDI/SVAP and HL7 FHIR (Fast Healthcare

Interoperability Resources) US Core release cycle. It was detailed on slide #15.

Al explained that USCDI+ goes beyond the definition of USCDI as a core set and a consistent baseline. He encouraged IS WG members to review the HealthIT.gov Buzz Blog post and USCDI+ Landing Page.

Arien thanked Al for the presentation and asked IS WG members to limit comments by trusting that the SVAP is the mechanism that the industry will use to adopt new, core, broadly accessible data for health information.

DISCUSSION:

- Steven Lane mentioned a comment Grace Cordovano raised between meetings that the USCDI (all versions) will be irrelevant to information sharing requirements in October 2022, when the expansion occurs.
  - Al responded that the USCDI will still be a subset of information included in the scope of all electronic health information (EHI).
  - Steven explained that previous HITAC/USCDI task forces that worked on the USCDI spent time dealing with the issue of wanting to add items to the USCDI where the implementation guides (IGs) were not fully mature. HL7 agreed to consider the recommendations of the previous USCDI TF. Also, he commented that USCDI+ will consider and potentially include additional items on top of the USCDI, and it will not go in another direction or use different standards. Arien commented that this work is just kicking off, so it will not be a focus of this workgroup.
- Raj Godavarthi asked for clarification on the process/timing interplay between FHIR US Core and the USCDI.
  - Arien stated that the mechanism is one where additional data classes and elements are considered for inclusion in the USCDI before the new version is considered for inclusion in SVAP.
  - Al responded that the publication of the final version of the USCDI triggers the update to HL7 FHIR US Core. Then, the SVAP may adopt the new version of US Core.
  - Arien described the ideal for a mature, standards-based framework and policy landscape.
- Steve Eichner asked if there is an expectation that USCDI+ will duplicate data classes or elements that are already in the USCDI. Or will it be completely different?
  - Al explained that USCDI+ will meet additional, specific use cases beyond USCDI; it will not duplicate USCDI, but it will build on it.
  - Arien described ideal use cases for the USCDI (as the floor, along with its inclusion in the SVAP) and USCDI+ and ways in which profiles could be added on US Core to address specialty field needs.
- Hans Buitendijk asked how the IS WG will assert the standard beyond vocabulary (based on previous work and discussions). Also, he asked Al to comment on the timeline for USCDI v2, which was shifted back because of the need for the finalization of the underlying standards, and USCDI v3, which is still in draft form.
  - Al responded that the annual cycle will now shift to the summer, and he described the process of the publication of the USCDI, followed by preparing/updating the complementary IGs, and finally the adoption of the new USCDI version by the SVAP.
  - Hans raised questions around the continued development of the USCDI, the stratification of data, and whether everyone will want to support expanded versions. He stated that when new items are proposed for the USCDI, the question of whether everyone will need everything in it will be raised.
  - Al responded that the USCDI is a requirement for certified EHRs and other Health Information Technology. There are some agencies that require the use of certified health IT, while others do not require this; systems can either shape their expectations and requirements around the USCDI (as a reliable baseline) or manage expectations for certified EHRs. ONC is trying to identify what the federal data requirements are and how

USCDI might continue to meet them in the future.
    - Hans raised the question of how one will draw the line between the USCDI and USCDI+, and Arien responded that the work of the IS WG is to evaluate which classes/elements will be entered into the set of interoperability elements that are considered standard for the nation (USCDI).
- Clem McDonald voiced his concern that vendors will not be regulated in how they send data after the October deadline, which will make it unusable as a standard.
    - Arien stated that the intention is to exchange in a structured way, but the consequence of the Cures Act requirement to share all EHI will be that the exchange of unstructured information will occur.
    - Al responded that ONC is not looking for vendors to actively convert their information into other forms, but the expectation is that, if health data is electronic, it must be available for sharing. Al explained that the information would be shared in response to a particular, valid request, so unstructured data would still be made available and shared, even if it does not have a particular standard.
    - Arien suggested that Clem review the Information Blocking provisions for more details.
    - Clem voiced concern that the USCDI+ will give groups an opportunity to escape using standards and asked if there are any methods for constraining them to use USCDI.
    - Al explained that the ONC Information Blocking team from the Office of Policy will address this at the February HITAC meeting and would gladly have a follow-up conversation with the IS WG if desired. Steven said that the co-chairs will determine if there is time for that presentation.

TOPIC: WORKGROUP PLANNING

Steven reviewed the charges of the IS WG, which included:

- Overarching charge: Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards
- Specific charges:
    - Due to the HITAC by April 13, 2022:
        1. Evaluate Draft USCDI v3 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.

Steven emphasized the need for the IS WG to focus closely on its charges and to add all outside comments and ideas to a parking lot document to address when/if the WG has the opportunity.

TOPIC: CHARGE 1A – DRAFT USCDI V3 NEW DATA CLASSES AND ELEMENTS

Steven invited WG members to submit feedback on Draft USCDI v3 content and to focus on the following questions:

- Are there any improvements needed in the data classes, elements, or their specified Applicable Vocabulary Standard(s) included in Draft USCDI v3, including:
  - Appropriate and meaningful data class and element names and definitions?
  - Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?
- Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?

Steven displayed a version of the New Data Classes and Elements in Draft USCDI v3 that he created in which he identified the submitters of each new item. He thanked the people who submitted the new classes/elements and highlighted the diversity of the submitters. Links to each individual submission were included in the document, which will be distributed to all WG members.

Steven invited IS WG members to begin to evaluate Draft USCDI v3 and to provide recommendations which may be appropriate for transmission to the HITAC.

DISCUSSION:

- Mark Savage discussed the comments he submitted, noting that they mainly indicated his interest in helping with the sexual orientation, gender identity, and functional/disability status elements. He suggested that the WG pick a few high-priority use cases from HITAC recommendations and to discuss what are the core data elements that are integral to those use cases but are missing from the USCDI. He suggested shared care planning and patient generated health data as potential use cases for focus.
- Steven stated that Gender Harmony will present to the IS WG at its next meeting on the definitions of sex assigned at birth and gender identity, including value sets and scope. Al and Steven discussed the upcoming presentations the IS WG will receive, which are listed in the Next Steps section (below). Steve Eichner offered to suggest speakers from the Centers for Disease Control and Prevention (CDC) to present on disability rights.
- Hung Luu commented that it looks like there are data elements missing under the Laboratory data class that would help recipients of data to interpret the test results they receive, specifically Instrument and Test Kit. The numerical value for certain important lab tests may vary depending on where and how the testing was done. In a more mobile world where patients receive care from multiple institutions, the inclusion of Instrument and Test Kit data are necessary to ensure that patient information is fully interoperable and variances in values do not cause confusion in result interpretation.
  - Al shared the link to the USCDI website showing the nine additional Level 2 items in the Laboratory data class, and he explained that the WG will have the ability to examine them as part of its later work. He encouraged members to table this discussion until that time.
- Arien described the existing code sets for race and ethnicity that are currently in USCDI v1, adding that though they are very detailed, they are capped at a minimum in the OMB code/vocabulary set. He explained that there is a large amount of specificity on tribal affiliation in a CDC code set and asked if the tribal affiliation proposed in the USCDI v3 is part of a larger conversation on how to recapture better and more detailed information on race, ethnicity, and tribal affiliation. He provided some illustrative examples.
  - Steven thanked him for his comments and noted that the IS WG will collect member input in a shared Google document on whether the items included in Draft V3 are appropriate or should be further clarified/modified or potentially removed from the USCDI v3. WG members should limit comments at this time to remove/modify.
  - Al listed several questions the WG could consider when regarding the elements - remove? Modify? Align with a specific code set? Develop a value set around the element?
  - David McCallie asked what degree of value set specificity is needed in the USCDI? Al

responded that it depends, and that ONC is conservative in declaring what an appropriate value set is, especially if there is not widespread consensus. ONC has defined terms within value sets when it was clear for previously included elements. David expressed concern that there would be unintended consequences where an implementor must include all possible value sets because the specifics have not been narrowed down by ONC. Being vague could increase the burden on interoperability. Al responded that defining value sets ensures that the implementor is meeting minimum values for data standardization.

- Steven encouraged IS WG members to look at the USCDI website and the submission itself. ONC has also shared its evaluation details and leveling assessments. Al shared a summary of ONC's evaluation process and stated that not all of the specifications included in a submission were included in USCDI v3.
- Steve Eichner asked who the consumers of the USCDI are for a data element or data class perspective. Al responded that it is everyone who uses an EHR or other certified health IT, including providers, patients, consultants, patients, and beyond.

- Clem commented that the Interpretation Code and the Abnormal Flag data elements were not included in the Laboratory data class, and these are often used by physicians. Also, he supported David's comments and stated that he would like to see a single code for every survey.
  - Clem and David discussed the need to work toward including more elements, and David stated that if the US Core includes these elements as part of the certification, specific value sets must be specified.
  - Steven explained that the previous USCDI TF 2021 asked its members to specify which of the data element is already in the C-CDA or US Core. This work will be shared with the WG members.
- Mark Savage commented on work that is underway at the Gravity Project that could be relevant to the WG. They are looking at whether they need to add information around the source and method for reporting race and ethnicity information. He stated that this could be useful for other data elements like sexual orientation gender identity, as well as v3 elements like functional status, mental function, and disability status.
  - Steven stated that these elements were already included in USCDI v2 and reminded WG members of the limits of the current charges. He invited WG members and members of the public to provide comments on past items or items that are at various levels of the draft USCDI. The WG may have an opportunity to review these comments as a part of its work on Task 2.
- Grace Cordovano described her experience submitting a data element and thanked Al for helping her during the process. She described how she called out her challenges navigating the ONC New Data Element and Class (ONDEC) Submission System within her submission.
- Michelle Schreiber commented that they have an internal process at CMS to gather feedback from stakeholders in the agency. They also have an outreach where they work with federal partners to identify the most highly promoted areas.
- Adi Gundlapalli commented on the CDC's internal process for coordinating work on data element submissions. They examined the elements from a public health perspective and decided which to promote.
- Grace commented that the structure and support inherent in the CDC's and CMS's processes are very different than the process faced by individuals/patients/consumers. She suggested that anyone who needs assistance or support during the submission process could reach out to a specific point of contact. Steven asked Al to comment on the changes that have been made or are planned for the submission/review process, in part based on the input of the USCDI 2021 Taskforce. Al responded that this could be discussed right before the USCDI v4 submission cycle.

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 set up with access to the document. Once you have gained access, you 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 comment only and may not add lines), consider these questions
  - Are changes warranted to these data elements, including definitions, examples, value sets? Should some of these not be included? If so, why (including significant barriers to adoption)?

- Are there significant barriers to implementation that warrant removing these data elements from consideration?

If there is time to discuss the general data elements during the meeting, the WG will go off these two documents.

The main topic for the February 8, 2022, IS WG meeting will consider specific asks from ONC on 2 Patient Demographics data elements from USCDI v2

- Sex assigned at birth
  - Consider realignment of USCDI v2 data element Sex (Assigned at Birth) with that of Gender Harmony's "Recorded Sex or Gender"
    1. This includes vocabulary (value set) and definition
- Gender Identity
  - Consider realignment of ONC value set with that of Gender Harmony project

WG members are asked to familiarize themselves with the following items to inform the discussion:

- USCDI v2 Patient Demographics – Sex (Assigned at Birth) data element
- USCDI v2 Patient Demographics – Gender Identity data element
- Review Gender Harmony Project context definitions

The Gender Harmony Project leads will present the Gender Harmony concepts in the context of questions from ONC in the Standards Bulletin and noted above in the homework item. WG members will be prepared to engage in a conversation with Gender Harmony to better inform the WG recommendations WG members may enter comments on this topic into the Google docs to keep track of individual thoughts.

Specific ONC requested topics:

- Patient Address – presentation scheduled for Feb 15 (with ONC's Project US@ lead Carmen Smiley, PhD, presenting)
- Functional/Disability Health Status – presentation tentatively planned for Feb 22 (who should be an invited guest presenter?)

The IS WG will recommend additional areas of interest for future WG meetings' focus on specific USCDI topics/domains.

IS WG members are asked to consider and identify any personal interest in ISA-related focus areas in which they are willing to dig deeper, perhaps in parallel with the Workgroup focus on USCDI over the next two months, for example:

- TEFCA standards enablement
- 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
- SDOH / Gravity data standards
- Race/Ethnicity vocabulary subsets, e.g., CDC
- Lab Orders/Results standards including SHIELD/LIVD, LIS to EHR/PH SYSTEMS
- Public Health data standards and potential PH Data Systems Certification
- eCR Standards
- Other ISA topics of interest

Public Comment

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

There were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR

Steven Lane: As noted verbally, members of the public are welcome to provide comment here during the course of the meeting AND to provide oral public comments during the last 5 minutes of our meeting. All comments provided become a part of the public record.

Hans Buitendijk: Based on the USCDI v2 review round experience and considering whether the exchange standards/implementation guides that are eligible for SVAP to support USCDI (C-CDA and FHIR US Core at this time) actually support the additions (already, next release, or separate guide not yet eligible for SVAP since it is not named in certification rule), how do you suggest that is considered in this round for USCDI v3?

Clem McDonald: I worry that USCD+ might generate different ways to do the same thing and be a problem to standardization. For example if Public health has their own + pathway. how do we keep it aligned with health care's vocabulary and structures. They should be the same i n many cases. They same could apply to quality etc. Granted that there will also be parts of content in a given plus category that does not overlap, But it takes work to see the sameness across partitions and there is a tendency for those in a given domain to see everything they do as unique. Hence my worry

Hans Buitendijk: @Clem: The challenge with USCDI is that it is intended to be supported by everybody, while USCDI+ allows for more targeted data that a smaller set should support. Just having USCDI would encumber more HIT than needed, while USCDI plus 1..n USCDI+ data sets could stratify who is supposed to support what. That introduces complexities as you indicate and potential of overlap if not carefully done that conflicts rather than complements. A proposed project in Argonaut is to look at how to "configure" multiple FHIR based IGs, with FHIR US Core at the "center" to manage this need for stratification.

Clem McDonald: Is there any data indicating the uptake of USCDI version 2. Since it is all voluntary would be nice to know the degree to which systems are adopting them

Hans Buitendijk: FHIR US Core that supports USCDI v2 was balloted and now going through ballot reconciliation.

Hans Buitendijk: @Clem: from an HIT perspective, until the underlying standards are rolled out and implemented, it would be hard to measure. After that, certification would be a good indicator that the necessary capabilities are deployed.

Steven Lane: We should all know when a vendor of certified HIT has opted to leverage a new version via SVAP.

Hans Buitendijk: @Steven: Correct. Until that time, it would be harder to measure considering that HIT can already have the capability, just not as measurable.

Mark Savage: "Irrelevant" from an info blocking perspective, but importation for national standardization?

Arien Malec: It's important from the perspective of sharing structured information. Full info-blocking exchange may include unstructured data, PDFs, etc.

Steven Lane: Full EHI exchange will REQUIRE the exchange of unstructured data in most cases.

Steven Lane: My understanding is that, when (some or all of) All EHI is requested, it must be provided in both machine and human readable format insofar as feasible.

Steven Lane: It seems that in future year's cycle we will have an opportunity to consider data elements promoted as a part of USCDI+ for inclusion in the core USCDI V4 and beyond.

Ken Kawamoto: This approach works if it's about optional additions. When making profiles that constrain, backward compatibility is not guaranteed unless it's decided that uscdi+ must be backward compatible to uscdi.

Arien Malec: Great minds think alike.

Ken Kawamoto: Another design principle to consider: when adding something to uscdi+, coordinate so there are not multiple different flavors of the new additions

Al Taylor: ONC Info Blocking FAQs https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Grace Cordovano: Avinash, that would be wonderful!

Ken Kawamoto: Agree with Clem - the natural state of USCDI+ will be all building their own, non-mutually interoperable versions

Ken Kawamoto: There will need to be deliberate intent and commitment to prevent that from happening

Steven Lane: Perhaps we could schedule an extra session for the discussion of Information Sharing and USCDI.

Christina Caraballo: Agree. We need a clear connection to USCDI and USCID+ if they are going to remain separate.

Clem McDonald: thanks Avinash

Ken Kawamoto: I have to go, my apologies. In addition to USCDI+ profiles being interoperable with USCDI, there needs to be an explicit consideration of the extent to which USCDI+ should be interoperable with one another, in particular when referencing the same data elements.

Al Taylor: Level 2 Data Elements in the Lab Data Class are listed here.

Al Taylor: https://www.healthit.gov/isa/uscdi-data-class/laboratory#level-2

Christina Caraballo: The doc that Dr. Lane put together that is on display is great. Can it be shared in our google doc? Looking at submission forms will be helpful and this doc is easy to access the info.

David McCallie: @steven - can you make sure we all have the right link to the more detailed documentation that you referred to?

Steven Lane: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v3

Al Taylor: @Christina We will look at the document to see the extent to which we can share.

Steven Lane: From the V3 page you can drill down to each item and from there to the submission.

Clem McDonald: Are we to understand that level 2 items that are not in USCCI 2 ro *[sic]* USCDI 2 are still to be discussed by our task group. Some of them are quite ripe

Steven Lane: Yes Clem, that is part of our charge, just not this month. :-)

Grace Cordovano: That would be really wonderful Al! Thank you!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

IS WG Webpage
IS WG – February 1, 2022 Meeting Webpage
IS WG – February 1, 2022 Meeting Agenda
IS WG – February 1, 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 meeting was adjourned at 11:58 a.m. E.T.