Health Information Technology Advisory Committee

Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | April 5, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) meeting was to finalize 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. The WG reviewed the IS WG Report to the HITAC. Then, the WG discussed the Phase 2 workplan and a list of suggested ISA topics.

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. Co-Chair Remarks
10:40 a.m. IS WG Report to the HITAC – PHASE 1 – RECOMMENDATIONS ON DRAFT USCDI v3
11:50 a.m. Establish Phase 2 Workplan
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
Jeff Ford, Department of Defense *(Attending on behalf of Thomas Cantilina)*
Christina Caraballo, HIMSS
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)*
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Leslie (Les) Lenert, Medical University of South Carolina
Hung S. Luu, Children's Health
David McCallie, Individual
Clem McDonald, National Library of Medicine

Mark Savage, Savage & Savage LLC
Abby Sears, OCHIN
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Hans Buitendijk, Cerner
Jim Jirjis, HCA Healthcare
Kensaku (Ken) Kawamoto, University of Utah Health
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)

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. Arien described the plan of work and agenda for the WG, including a review of the draft of the WG's recommendations letter and report to the HITAC. He stated that the WG would review the ISA portion of its work if time allowed.

Steven invited all attendees to share comments, questions, and feedback in the public chat in Zoom. He 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 there was one outstanding item of focus in the draft report to the HITAC, and he encouraged WG members to reserve time to begin work on Phase 2.

Al offered to display both the recommendations letter and report, which were previously shared with WG members via email.

TOPIC: WORKGROUP WORK PLAN

The co-chairs briefly 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:
    - Phase 1: 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
    - Phase 2: 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: IS WG REPORT TO THE HITAC – PHASE 1 – RECOMMENDATIONS ON DRAFT USCDI V3

The co-chairs provided an overview of the IS WG Phase 1 Recommendations to the HITAC on Draft USCDI v3 document. Steven explained that the WG's previous working documents and spreadsheets were translated into the format of a letter, report, and accompanying slide deck and that the WG would review them to ensure that all relevant recommendations and information were included.

Steven shared the following introduction to the subsection New Data Classes and Elements: "As part of its Phase 1 work, the IS WG reviewed all of the recommendations from ONC for new items to include in Draft USCDI v3, and the WG supports them all across the board, with modifications (included in the IS WG Recommendations Report and Letter to the HITAC) which are simply intended to make them more understandable and to support the logic/structure of the USCDI in response to the stakeholder input."

Arien reviewed previous WG discussions and highlighted key areas of the draft document. WG members shared feedback, and the co-chairs noted that any outstanding spelling or grammar issues would be fixed during offline work prior to submitting the document to the HITAC. Steven reviewed the additional WG recommendations, which were included at the end of the document; he noted that this is where the WG is asking ONC to extend its charge for future work. The co-chairs thanked the ONC team for their support.

DISCUSSION:

- Arien explained that Hans, who was not able to attend the meeting, did an analysis with HL7 and Fast Healthcare Interoperability Resources (FHIR) elements that are not ready. Steven added that the WG is aware that what they have proposed may pose challenges for HL7 in terms of readying the appropriate implementation guides (IGs), though the WG also acknowledges that ONC and HL7 have processes in place to assure that all items will be supported.
- In response to a question in the Zoom chat, Al stated that the document is not available for public review as it is still under deliberation by the WG and has not been forwarded to or approved by the HITAC. Then, it will be posted on the HITAC website as meeting materials and will become part of the public record.
- Arien explained that they reviewed the suggested addition to add the calculated average value of the systolic and diastolic blood pressure calculated across multiple readings, noting that this was a frequently made public comment from the American Heart Association (AHA) and the American Medical Association (AMA). Arien added that the AMA and the AHA made recommendations for how these readings should be taken, including how measurement errors should be handled. He reviewed the WG's previous recommendation that ONC work with LOINC to better assess how to capture this information, either via a new set of LOINC codes (for systolic and diastolic) or using an observation modifier noting that the systolic and diastolic are the averages of multiple values. WG members discussed how to support the recommendations from the medical societies that these are important values to capture for interoperability but that more work is necessary to determine the appropriate representation.
    - Steven commented that there are other vital signs for which ONC has been compelled to accept calculated values and described several examples of how many systems already only show the average of three blood pressures. However, specialty systems that do not need an average could still receive single readings. He supported Arien's point that more clarification is needed.
    - Clem commented that the usual recommendation is to calculate an average value when the first blood pressure reading is high, which allows for more accurate measures. Multiple readings are not always done.
    - Ike asked for confirmation that systolic and diastolic blood pressure would be averaged separately, and Al explained that there are separate data elements for systolic and diastolic. The clarification needed is if the recommendation is to add systolic and diastolic blood pressure, as well as the computed mean averages. Arien suggested that ONC work with LOINC and other stakeholders to ensure that correct coding and data representation is used but is not recommending how to correctly represent these values now. Clem commented that there is no option for a modifier for any of these values at this time. Ike asked if there is a need to share whether the blood pressure readings were taken multiple times and why. Arien commented that the WG supports the AMA and AHA recommendations and will let ONC and LOINC determine the representational issues.

- WG members discussed previous recommendations around Clinical Notes and Grace's question about whether Tumor Board Notes should be called out separately, like Surgical Operative Notes.
  - Steven commented that his organization has had several discussions around calling out Tumor Board Notes and explained that they determined that this could be contentious practice, as the Tumor Board meets before options are presented to the patient.
  - Grace responded that there is no transparency, documentation, or information on the Tumor Board's process that can be shared with the patient. She shared a recommended LOINC code, and Steven stated that it looked like the correct code.
  - Arien commented that this information would be shared with the patient in the Designated Record Set (DRS). Clem agreed that this information is covered by a code and is already included in the DRS.
  - Steven reviewed the specific IS WG Recommendation 16, which recommended that the USCDI v3 include all note types coded in the LOINC Document Ontology, with a special call-out of Surgical Operative Notes. Grace also recommended including a call-out of Tumor Board Notes, as it is particularly valuable to patients. Individual note types were not leveled by ONC, so this recommendation is valid. WG members discussed the shortlist of note types that are currently being shared and how healthcare organizations have handled this in the past. Al commented that there is a difference between the scope of Information Blocking being the USCDI and how requirements will be fulfilled once the USCDI is no longer the limit of Information Blocking; anything that is captured by electronic health records (EHRs) will have to be exchanged to avoid Information Blocking.
  - The WG reviewed the updated working draft of the recommendations document.
- Mark shared several comments on the IS WG's recommendations, noting that some nuances from the original WG working documents were not translated over into the report. These included:
  - In Recommendation 06, that ONC add a value capturing the intent to become pregnant, he stated that the WG should explicitly state its support for adding Pregnancy Status as a data class. Steven commented that the WG is already supporting the inclusion of all the data classes and element ONC recommended for inclusion in USCDI v3, including Pregnancy Status.
  - He asked why Recommendation 09, that ONC assess referencing a value set based on the International Classification of Functioning, Disability, and Health (ICF) model for use within the Health Status/Assessments data class, was split. The co-chairs discussed the formatting and commented that Recommendation 09 should be added as a sub-recommendation under Recommendation 25. Clem commented that ICF does not fit into FHIR, and the WG discussed how to update its recommendation that ONC explore using and naming ICF as a useful tool in the documentation of disability, as it is broadly used. The WG heard testimony supporting the use of the ICF but that it is not the only item that could be used in this context. Al recommended also moving this new, combined recommendation up within the formatting of the document.
  - The WG removed a bullet in Recommendation 09 and updated the wording of the recommendation in the now combined 09 and 25 recommendations to indicate that the WG supports changes or definitions for Disability Status, Functional Status, and Mental Function/Cognitive Status data elements in the Health Status data class. Ike asked if there is a different acronym for ICF that is used for public health, and the WG discussed the question. A public commenter shared a link to the Centers for Disease Control and Prevention's fact sheet on the topic. WG members referred to testimony that the WG received and previous discussions. Arien described how the suggested codes and value sets that were listed for ONC's consideration were developed and rearranged the listings for clarity.

  - He reviewed Recommendation 22 and asked about the reasoning behind how the WG's recommendations on the Gender Identity, Sex for Clinical Use, and Recorded Sex of Genders data elements were divided. Arien described his process, and the WG agreed to add contextual statements that the source and method of the collection of data for Sex for Clinical Use should be tracked. The wording in the document was updated.
  - Was the inclusion of Coverage Type as a data element in the Health Insurance Information data class accidentally omitted from the WG's recommendations? The WG reviewed its working documents and found an initial recommendation; Al explained that he would transfer this recommendation over into the final recommendations document.
- Clem asked for clarification on Recommendation 10 that the USCDI v2 specify SNOMED-CT as an applicable vocabulary standard for the Specimen Type data element in the Laboratory data class. Clem stated that HL7 already recommends a code set for Specimen Type, which he shared in the chat, and he suggested that this be mentioned in the recommendation.
  - Al updated the recommendation with a sub-bullet that SNOMED-CT is not meant to replace it, but it is an applicable vocabulary standard. Al described ONC's process for determining commonalities between which value sets are used.
- Steven commented that two of the recommended Laboratory data elements that were included in Recommendation 24 were not included at Level 2 in the USCDI.
  - Arien noted that he crafted the recommendation and that he could identify the sources that would allow for the inclusion of the Unit of Measure and Interpretation data elements. Test Interpretation is in Level 1 and Unit of Measure is under Result Value in Level 2. Steven stated that the WG's charges declare that Level 1 and the Comment Level items are less mature than Level 2 items; therefore, they are not eligible for inclusion in USCDI v3.
  - Interpretation was moved to the recommendation around items for future consideration by ONC.
  - Hung commented that a recommendation to add SNOMED-CT as an applicable standard for Specimen and Qualitative Results was included in the working document but was left out in the recommendations document. WG members discussed whether it was already included in the recommendations, noting that it was listed in Recommendation 18, and they updated the text. WG members discussed the appropriate ordering of the recommendations and made adjustments to the document.
- Clem supported the WG's recommendation encouraging ONC to explore whether LOINC codes for Vital Sign Qualifiers should qualify for Level 2 and for inclusion in a future version of the USCDI. Steven supported this recommendation.
- Arien discussed his comment on Recommendation 13, in which he asked if the WG made the recommendation for only patient generated versions of the data cases listed in the recommendation or all versions of the data. He stated that in all of the cases, there are objective sources, as well as patient reported.
  - Steven asked if this should be moved to be a part of Recommendation 12, and Arien asked if any of these data elements were already included in the USCDI. Al confirmed that the elements are all Level 2 but not already included. Arien recommended that the elements be included in USCDI v3, and to be consistent with the WG's other recommendations that both clinical observations and patient-generated health data would be sources. WG members and Al discussed whether all elements listed could be both clinical observations and patient-self-reported and confirmed that they could.
  - Steven recommended removing the examples listed after each data element and that the Provenance/Metadata for these elements should state whether the data was derived from clinical observations or patient reported.

Establish Phase 2 Workplan

IS WG members reviewed the specific Phase 2 charge (listed above), and AI described the Interoperability Standards Advisory (ISA) update process ONC follows every year, including updates to the ISA Reference Edition. He reviewed the ways in which the ISA can be used and how the WG could make recommendations for changes to the ISA. Arien explained that he and David McCallie were co-chairs for the Interoperability Standards Priorities Task Force 2021 and described their work process and resulting recommendations. He discussed how the ISA is related to the certification process and how it can be used to mature standards and guidelines for future certification.

Arien highlighted the following potential areas of focus for the WG:

- Social determinants of health (SDOH) Standards
  - Gravity Standards
  - CDC Race/Ethnicity vocabulary subsets
- Lab Orders/Results
- SHIELD/LIVD, LIS to EHR/PH SYSTEMS
- CDC
  - Public Health (PH) Data Systems Certification
  - Electronic Case Reporting (eCR) Standards
- Others

Steven noted that the WG has nine public meetings scheduled for its Charge 2 work, and a list of upcoming Charge 2 IS WG meetings was included in the presentation slide deck. Christina recommended looking at connecting between the ISA and the USCDI and how to map ISA to the USCDI. She offered to put a recommendation together to share.

Action Items and Next Steps

- Individual WG members were reminded that they can submit public comments on the Draft USCDI v3 or Level 2 tabs on www.HealthIT.gov/USCDI for those recommendations the WG is unable to include but that members would like to advance to ONC.
- The WG will prepare 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 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.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There was one public comment received verbally:

Debi Willis, PatientLink and HL7: I want to ask, logistically, how to move forward in getting the patient request for corrections to become part of standards. There are so many errors in charts, and I'm a co-chair of the Patient Empowerment Workgroup in HL7 and a co-lead on the Patient Requests for Corrections project. We are now going to go to ballot in May, but it's really important that we move this forward to actually get it implemented. Getting it in front and noticed in the standards is really critical. Are there recommendations on what we should do, and are you are looking into this is there anything we can do to help?

Steven: I can respond quickly. We have Grace as a great voice on this workgroup, as well as the public comment process. Certainly, anyone can jump onto the ISA and put their input there. But there's not any question that we will be addressing this. As we have in the USCDI phase of our work, we will have the opportunity to hold hearings and to invite subject matter experts, etc., so I anticipate this may be one of those situations where we will do that. And, probably in our meeting next week we will talk about what are the areas that warrant that kind of a laser-focus. It is going to happen.

Arien: Just to repeat: our first activity will be to prioritize the list of things and this is clearly part of the set that we will contemplate and consider.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the Interoperability Standards Workgroup! Please remember to change your chat setting to "Everyone" if you would like all to see your comments.

Kelly Aldrich: Apologies for being late - thank you

David McCallie: It's not measurement error, rather it's to account for transient volatility in the patient's BP, I think.

Steven Lane: +1 David

Kelly Aldrich: So is that average mean along with SBP and DBP display?

Kelly Aldrich: Which is different then average of multiple recordings

Al Taylor: @kelly Presumably this would be "average diastolic" and "average systolic" blood pressures, as opposed to "mean blood pressure"

Grace Cordovano: Page 9: IS-WG-2022-Phase 1 _ Recommendation 16: regarding "when notes are collected, they should be indexed with the appropriate LOINC code…" in addtion *[sic]* to surgical notes, may we also encourage Tumor Board Notes (https://loinc.org/85231-9/)? Would clinical decision supports outputs also potentially fall in this category of notes?

Kelly Aldrich: The meaning for clinical application is in the mean perfusion of the brain, lots of ICUs use the mean to titrate drips

Kelly Aldrich: And don't use SBP / DBP - just FYI

David McCallie: It doesn't seem like we need a new data element class - this is just a specific vital sign to be considered in some cases. Just another code, not a new data class?

Kelly Aldrich: BPs are now used in multiple calculations of deterioration - need clarification agree

Arien Malec: It's not MAP, it's the average of multiple readings.
https://www.healthit.gov/isa/taxonomy/term/1391/level-2

Debi Willis: Agree with Grace.

David McCallie: If we call out for all LOINC coded notes, why do we also need to call out specific note types? There are dozens of other "useful" note types that could be mentioned?

Mark Savage: What is process for flagging items in letter that need or may need adjusting to worksheet? Not sure whether current process will get to items I'm spotting.

Carmela Couderc: https://www.cdc.gov/nchs/data/icd/icfoverview_finalforwho10sept.pdf

Steven Lane: @Clem - Which recommendation # is Specimen Type?

Carmela Couderc: Should the name of the data element be Specimen Type or Specimen Source?

Steven Lane: https://hl7-definition.caristix.com/v2/HL7v2.8/Tables/0487

Steven Lane: https://www.hl7.org/fhir/v2/0487/

David McCallie: are there any systems that don't include "interpretation"?

David McCallie: Thanks Steven 🙂

David McCallie: If it is observed, then it's not patient reported

Kelly Aldrich: Thank you - no adds

Maria Moen: As a long-standing member of HL7's patient empowerment workgroup I will commend you as a team for acknowledging the value of patient reported data. Thank you!

Debi Willis: The patient empowerment workgroup is working on a project to provide a way via FHIR for patients to request a correction/amendment to their record. Where would/could that fit?

Grace Cordovano: Great point Debi! We have come up with robust recommendations but many of these data classes and elements will need avenues for patients, families, and clinicians to be able to correct errors in the medical record.

Steven Lane: https://www.healthit.gov/isa/

David McCallie: @Arien - didn't the last ISA TF leave a list of "for future consideration" - that could be brought forward for consideration?

Arien Malec: Yes.

Steven Lane: To fully interact with the ISA you will need to create an account @ https://www.healthit.gov/isa/user/register

Arien Malec: A number of additional areas of potential interoperability standards priority were identified by the Task Force members but were unable to be fully addressed in the limited time available. We feel that future work is warranted in the following areas:

- Care Plans/Chronic Dx Management
- Data Sharing Between Federal & Commercial Entities
- Portal Data Aggregation Across Multiple Portals
- Occupation and Location of Work
- Data Exchange Formats for Price Transparency

Arien Malec: We also have requests to add standards for patient use of HIPAA rights to self-correction

Ram Sriram: Considering that AI will play a role in future Health IT, will there be any discussion on what kinds of standards will be needed for this.

Steven Lane: Most recent 2022 ISA Reference Edition: https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf

Debi Willis: With the high rate of errors in charts, we really need a standard way for patients to report errors and have those correction requests shared in an interoperable way.

Grace Cordovano: +1 Ram; I would advocate for developing standards for exchange of AI/ML clinical decision support outputs.

Debi Willis: Having accurate data is so important for AI and patient care.

Grace Cordovano: Yes, agree Debi!

Ram Sriram: @Grace: This would require looking into semantics, I believe

Grace Cordovano: @Ram: some work here via HL7
https://confluence.hl7.org/display/CDS/Clinical+Decision+Support+Standards

Mark Savage: Can help with both Gravity and CDC R/E subsets.

David McCallie: There are a number of non-health IT-specific new standards that might be relevant to consider, such as a new provenance standard from Adobe, MSFT and others - C2PA which might make PDF-based sharing of authenticated documents easier

Carmela Couderc: The OMB race and ethnicity categories are also defined in the CDC Race / Ethnicity code system - same code system, multiple, use case specific value sets.

Grace Cordovano: To @Debi's points, here is more information from the HL7 Patient Empowerment Work Group on Patient Request for Medical Records Implementation Guide: https://build.fhir.org/ig/HL7/fhir-patient-correction/

Ram Sriram: @Debi: There are some interesting issues here: 1) trust in data for ML applications; and 2) algorithm bias.

Arien Malec: @Carmela — yes, the OMB codes are the required subset, and while people can draw from the wider subset, they don't often…

Mark Savage: +1 to Debi Willis's comment. Can help on this issue, at least from policy/HIPAA perspective.

Debi Willis: Thanks Mark. I would love to connect. My email is Debi@MyPatientLink.com

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

IS WG Webpage
IS WG – April 5, 2022 Meeting Webpage
IS WG – April 5, 2022 Meeting Agenda
IS WG – April 5, 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 next meeting of the IS WG will be held on April 12, 2022.

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