



# Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

## Meeting Notes | March 29, 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 were no public comments submitted verbally, but 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.	IS WG Draft USCDI v3 Member Recommendations
11:50 a.m.	Upcoming Charge 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

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

Sanjeev Tandon, Centers of Disease Control and Prevention (*Attending on behalf of Adi Gundlapalli*)

Jim Jirjis, HCA Healthcare

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  
Ram Sriram, National Institute of Standards and Technology

## MEMBERS NOT IN ATTENDANCE

Thomas Cantilina, Department of Defense  
Kensaku (Ken) Kawamoto, University of Utah Health  
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)  
Abby Sears, OCHIN

## 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 for the WG, noting that work will soon shift from the shared documents to a draft of the WG's recommendations letter and report to the HITAC. He encouraged WG members to begin to review the draft recommendations letter and report and asked everyone to share feedback on items that were not included in the documentation. Arien invited WG members to incorporate editorial updates within the documents and to leave notes in the margins with more complex comments.

Arien reviewed the agenda for the meeting, and 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 provided an overview of the meetings the co-chairs have taken with HL7 and other organizations to ensure that the WG's recommendations would be ready for nationwide exchange in terms of applicable implementation guides (IGs) and health IT vocabulary standards. They learned about challenges and items that were reasonable and offered to share the feedback with the WG.

Steven responded to a question that Hans has raised several times over the years, which was, "What is expected when an item is added to the United States Core Data for Interoperability (USCDI), and what kinds of burden does this place on stakeholders?" He encouraged the WG to consider that not every system must have a process for collecting every data element; rather, all systems must simply be able to accept the data when it is sent. Arien discussed how information that is collected but has yet to be coded is handled, adding that there is a difference between data in the USCDI being required to be interoperable versus an implied mandate to collect it. This is part of the transition of the USCDI from core data to data across the continuum of care (including specialty providers).

### 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:
  - 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 (submitter: Hans Buitendijk)
  - Related Person Name and Relationship
  - Tribal Affiliation
  - Reason for Referral
- Average Blood Pressure (submitter: Clem McDonald)
- Health Status data class
  - Use of International Classification of Functioning, Disability and Health (ICF) (submitter: Hans Buitendijk)
  - Expand Mental Status with additional supplements and examples
- Laboratory data class (submitter: Hung Luu)
  - Instrument Unique Identifier data element
  - Specimen Source Site data element
  - Test Kit Unique Identifier data element
  - Values/Result Status data element

## DISCUSSION:

- Clem reviewed the recommendation that he submitted to expand the Mental Status data element under the Health Status data class to include a list of sub-items as examples. He stated that they are important and necessary for capturing information about rising rates of drug and alcohol use and addiction.
  - WG members agreed with Clem's suggested and briefly reviewed the list of examples that would be included in the WG's recommendations to the HITAC. Value sets indicating drinking/alcohol use and smoking status were included in the recommendations.
- Clem reviewed the recommendation that he submitted to include all questions under a name/LOINC code for a panel or survey.
- Clem discussed the recommendation he submitted about including qualifiers for the measures for the Vital Signs data element (i.e., standing, sitting, cuff size, use/not use).
  - Arien commented that this topic came up during the WG's discussion about averaging multiple observation values for blood pressure, which has been a frequent public comment from the American Heart Association (AHA). In offline conversation, the co-chairs determined that the AHA comment would be best handled by the qualifiers listed in the WG's recommendation. Arien noted that Vital Signs, Dates, and Timestamps are Level 2 data elements, but qualifiers are not yet in Level 1 or 2. Clem suggested that the recommendation be clarified based on the AHA's specifications on their website. Clem offered to share a list of commonly used qualifiers. Steven discussed inconsistencies around what is meant by an average and stated that ONC has left systems to determine how they will do this calculation. WG members discussed how to average multiple observations based on algorithms.
  - Following a discussion, the WG decided to add a recommendation that ONC work with stakeholders and LOINC to specify how to appropriately represent the Vital Signs qualifiers, either as a modifier or as a new LOINC code. A determination must be made to ascertain if



they would be included in Level 2 for future consideration for the USCDI.

- WG members discussed previous recommendations around Operative Note and Narrative Note and the variety of opinions; one interpretation is that all clinical notes should be made available with assigned LOINC codes, and the other is that changes could cause substantial burdens on developers.
  - Hans stated that Narrative Notes are currently captured within Clinical Notes without a defined structure or the specification of discrete data inside the note. LOINC codes are then used to indicate the kind of note. If the intent is to provide more structure to notes, a more complex recommendation would be that the LOINC codes still apply, but the data is more structured using a set of document codes. Then, there is a need to determine which codes are used.
  - Arien described offline work on this topic and proposed that the WG refer only to narrative notes and their content, not structured documents, which are a matter of implementation guidance and will be dealt with by the ISA. The WG already has a recommendation that calls for narrative notes to be LOINC-encoded and does not call for all electronic health records (EHRs) to capture all LOINC codes. The WG's proposals are for work going forward, so a default modifier could be used to identify legacy data or previously captured clinical narratives that were/are not linked to a specific LOINC code. Clem highlighted David's comment in the public chat, in which he agreed that the exchange of unstructured narrative is a must-have and that the focus on unstructured data can be difficult. David agreed that there is a need for a catch-all code for legacy data that did not have a LOINC code when it was first captured.
  - Following a clarifying discussion, Arien shared a link to the previous discussions the WG held on this topic and offered to review the recommendation to ensure that all opinions were properly captured. Hans and Arien reviewed the wording of this and previous/related recommendations; Steven updated the WG's spreadsheet.
- Hans reviewed his comment on the Related Person Name and Relationship data element under the Patient Demographics data class and explained that more clarity is needed because there is a potential overlap with the Care Team data element.
  - Steven commented that Related Person is a personal relationship to the patient and not meant to be a member of the care team or financial guarantor. Hans suggested that ONC should clarify this element and commented that the use case should be updated for this element to reflect its intended use.
  - Al thanked the WG for the request for clarity and noted that the original intent was to provide the definitions necessary for records linkage (i.e., Maternal/Child) and to associate a demographic or clinical result between a family member and a patient (i.e., Blood Type). He added that it would also be useful for patient matching (e.g., between twins, a newborn and parent). ONC will provide additional clarity and use cases in the final USCDI v3.
  - Hans and Mark supported additional clarity, and Mark referenced a comment he made in the document previously that there may be an overlap in the terminology descriptions between Care Team and Related Person in the standards. Hans responded that the distinction has been made on the standards side and suggested a variety of options for the WG. Mark commented that the definitions need to be updated, and Hans agreed.
  - Grace commented that her understanding is that this is meant to be the primary care partner or the person who is coordinating the care for the patient and arose out of issues related to the no-visitor policies during the COVID-19 pandemic. She highlighted differences between the executor of a patient's estate, the next related person, and the primary care partner. Steven asked if there is a value set she recommends or if it is a free text field, and Grace commented that a use case would be to not block information (under HIPAA) to people who are responsible for the daily care coordination for a patient. Hans supported Grace's examples but suggested that they would be applicable to the Care Team data element. Al agreed that Grace's examples would be captured under Care Team Member and Care Team Member roles. ONC will make the necessary clarifications to ensure that all



relationship information is captured.

- The WG discussed the recommendation that data captured for persons consulted in the care of the patient belongs in the Care Team data class and elements. The purpose of the Related Person Name and Relationship data element is to capture simple demographic-based information on relationships that do not reflect the responsibility for a patient's care, financial, or other responsibilities. AI confirmed that this was ONC's intent. They included mother's maiden name and next of kin as examples that would support patient matching, and AI suggested updating the scope of the recommendation. Mark commented that the WG's final recommendations should address the potential overlap of the two data classes, and AI suggested clarifying definitions of them both to better distinguish between them. Hans suggested that if the intent is for the purpose of patient matching, it should be stated clearly. WG members discussed the use of this information for patient matching. Ike commented that the issue is the definition of a care team, as well as how the definition changes over time as consumption of the USCDI expands across new participants. The WG could recommend that ONC review the definition in the future. Arien shared the proposed text in the public chat in Zoom.
- Steven updated the WG's recommendations based on the WG's discussions. The co-chairs will update the text during offline work.
- Mark reviewed his comment on recommendations around including the data elements of Disability Status, Functional Status, and Cognitive/Mental Status under the Health Status data class in USCDI v3. He explained that the recommendation that the USCDI reference the International Classification of Functioning, Disability, and Health (ICF) as a data set should be updated to indicate that it should not be used for Disability Status because community experts state that this information should be self-reported using the ACS and Washington Group questions. ONC should explore whether the ICF value sets should be included for the other data elements.
  - WG members agreed to support Mark's recommendations.
- Clem asked if the Reference Range and Normal/Abnormal Range data elements could be recommended for inclusion in USCDI v3. AI responded that they are not at any level of the USCDI, as they have not yet been submitted for inclusion by stakeholders, so they are out of scope for the WG at this time.
- The WG discussed Hung's recommendations around including the Specimen Site and FDA Test Kit Unique Identifier data elements under the Laboratory data class in USCDI v3 as the applicable standard or value set. Steven provided an overview of the WG's previous discussions and justifications.
  - Arien commented that the WG could consider incorporating everything into Level 2 that is part of the CLIA-defined value set for transmission. He offered to find all the Level 2 attributes that are also in CLIA, which would include Results Status, Date and Time, Source Site, Test Interpretation (Level 1), and Reference Range (not included in either level). Hans commented that Test Kit Identifier is challenging to include because the ability to capture this at the level of interest (Unique Device Identifier, UDI) is difficult/possibly not viable, and he described related challenges. At best, a higher-level identifier could be used, and he cautioned against creating additional burden of requiring the inclusion of the Test Kit Unique Identifier. Also, he commented more broadly that not all health IT users should be required to support all elements, and Arien responded that the intent was to include all items that are critical for the interpretation of a value in context.
  - Steven asked for WG members to share feedback on whether the WG should substantially change its recommendation. Clem stated that not all test kits have codes and that over 50% of lab tests are not FDA approved and do not have codes. He stated that input is needed from labs to gain deeper knowledge, though he does support the others' suggestions. Hung commented that Test Kit and Instrument Identifiers are required elements and that public health agencies require the reporting of this data for COVID-19 testing. These are already required elements (and burdens) on labs, and EHR systems have already been asked to



support this data in the real world, despite the lack of standards or inclusion in the USCDI. He suggested that having a field in USCDI to support this information would be helpful, even if not every test kit has a UDI. Hans stated that the LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Tool is not required to support this, while FDA SHIELD has begun work on it. While it is possible to capture this information, it is difficult, and though the standards could accommodate this requirement, the practice and process are not yet supporting it. Hans described issues related to the source's inability to provide this information, even though systems can receive it.

- Ike commented that public health requires the reporting of this data, which typically comes out of a Laboratory Information System (LIS) in addition to potentially coming out of an EHR. If there is a standard in place in the USCDI, it provides an opportunity for it to be included in EHR standards, which enables hospitals and other users of EHRs to have a specified place for this data. This makes it easier for them to transmit it to public health and gives hospitals the opportunity to attach information. He recommended including it in the USCDI. David agreed on the value of this information for patient care, and the burden created should not stop the inclusion of this element.
- The WG discussed the amount of burden this recommendation would create and decided that the WG should recommend that it be included in the USCDI and required if available. Arien suggested including the Unit of Measure (UM) data element, as well as recommending the future inclusion of the Reference Range. AI clarified that data elements in the USCDI include the ability to be captured and exchanged. Arien discussed reasons to capture this data for downstream purposes. Steven updated the WG's recommendations in the spreadsheet.
- The WG noted that Medications has a long list of items leveled lower and in the Comment Level but added that those would be discussed later. AI invited WG members and members of the public to input their feedback on all elements and classes in the USCDI system for public comment on the website at <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.
- Grace stated that she submitted a comment in ONC's New Data Element and Class (ONDEC) Submission System asked if Tumor Board Notes should be called out, specifically, as an item for inclusion in the USCDI.
  - Steven asked if Tumor Board Notes are identified with a LOINC code, and, if so, the WG has recommended that all LOINC coded notes must be transmissible. He also inquired if they are part of the designated record set (DRS) and, if so, HIPAA and Information Blocking provisions could come into play.
  - Grace asked if the Clinical Decision Support Outputs data element would be included with the WG's recommendations on clinical notes. Steven stated that if they are not included, the WG should discuss these topics during the next phase of its work. Mark commented that the USCDI Task Force 2021 addressed this question previously, and he added that, at the time, Dan Vreeman commented that there was an associated LOINC code. Steven stated that the WG could investigate whether these notes are being coded appropriately in certified health IT systems.

## Action Items and Next Steps

IS WG members were asked to capture their thoughts and recommendations between meetings in Google documents that informed the WG's recommendations and streamlined the conversations. Members should share a Google email address with ONC's logistics contractor at [onc-hitac@accelsolutionsllc.com](mailto: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).

- The WG will continue to 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.
- Friday, March 25, 2022, was the cut-off for new recommendations on the editable spreadsheet.
- The WG will not be able to work through and discuss every one of the 70 recommendations, so WG members were asked to please review other lines to identify which should be prioritized by the WG.
- 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](http://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. 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 were no public comments received verbally.

### QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Arien Malec: Reminder for Everyone to use "Everyone" in the chat.

Steven Lane: Thank you Hans, as always, for your willingness to contribute to the effort in this way.

Matt Reid: Average blood pressure is already Level 2

David McCallie: The combinatorics of all those qualifiers can get messy! "left arm, small cuff, sitting" Pre-vs-post coordination will have to get worked out

Arien Malec: Average BP is a L2, but there's no current clean way to collect it (there's no LOINC code) — the modifier is the best way we hit on...

David McCallie: Systems simply must be able to exchange narrative notes, regardless of how much "burden" exists!



Steven Lane: Entry #8

Steven Lane: Scroll up

Clem McDonald: dave I agree with you 100% find my self agreeing more and more

Arien Malec: Narrative-only

New clinical notes must be able to be mapped and use a default if one can be established/agreed to.

For existing clinical notes

Do not require recoding.

Pick a sensible default recommend that Regenstrief to create a new LOINC code to serve as a generic default, e.g., "Clinical Note" as the ontology does not seem to have such a general root.

Best practice is to:

Punt to AI/NLP to determine clinically + work flow appropriate.

Consider a 'top 10' for priority for best effort legacy mapping

Carmen Smiley: Dr Lane's interpretation is correct

Mark Savage: I think the recommendation needs to ask for clarification of the data element definitions--both care team member and related person.

Mark Savage: \*needs to include clarification

Joel Andress: wouldn't we want the field to support as broad a context as possible, or to at least leave open the possibility of doing so in the future?

Grace Cordovano: Care Team Member: The person responsible for a patient's routine care and care coordination who needs to receive all essential updates on a patient's health status, conditions, and be the included in all conversations pertaining to an individuals *[sic]* care and treatment decision making.

Hans Buitendijk: Interestingly, mothers maiden name or simple demographic relationship without a particular role in the process, they would end up in different places. In FHIR we have an extension attribute of mothers maiden name on the Patient *[sic]* for matching purposes and simple demographic relationship withot *[sic]* responsibilities in RelatedPerson.

Joel Andress: In the ideal state, individual data elements will support multiple use cases. Does it make sense to specify the USCDI requirement to support as broad a set of those uses cases, rather than segmenting them off to a single purpose?

Mark Savage: +1 @Joel

Arien Malec: We recommend that this data element be clearly specified as limited to simple demographic relationships, e.g., for the purpose of improving data matching, and is not intended to imply participation in the care of the patient for any purpose.

Grace Cordovano: To confirm, Arien that is for line 57

Arien Malec: We'd note to consolidate...

Grace Cordovano: Thank you

Hans Buitendijk: The other comment was that in the Tribal Affiliation *[sic]* references to standards it includes both a reference to vocabulary and to C-CDA and FHIR standards. Given USCDI is only focusing on vocabulary standards, the references to FHIR and C-CDA should be removed. I.e., these references "HL7 FHIR: US Public Health Tribal Affiliation extension HL7 CDA: Tribal Affiliation template HL7 Value Set:





TribalEntityUS" are not about vocabulary but format although they in turn reference vocabulary that should be referenced directly in USCDI (e.g., FHIR references <https://terminology.hl7.org/3.0.0/ValueSet-v3-TribalEntityUS.html>)

David McCallie: a generic high level textual description (not UDI) would still be useful downstream

David McCallie: Time for Arien's annual reminder of Postel's law?

Arien Malec: For reference, here's the CLIA set

Arien Malec: <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR9482366886d579f/section-493.1291>

Hans Buitendijk: FDA's SHIELD is focusing on this topic.

Arien Malec: Missing elements currently are UOM, reference range, date/time, status, interpretation, specimen source

Arien Malec: We already propose including source and status in USCDI V3

Hans Buitendijk: LIVD has a place for it, but LIVD is not a required tool yet.

Arien Malec: All but reference range are available in L1/L2

Hans Buitendijk: And valuing *[sic]* it is very hard at the UDI level.

David McCallie: "if you have it, you SHOULD send it"

Hans Buitendijk: While ELR was asked to include and has a spot for it, but same problem as it cannot be captured electronically.

Arien Malec: Required if Present...

Hans Buitendijk: Clarification that the ability to receive will vary by EHR - it may not be as big a concern, but needs validation (which I will be seeking).

David McCallie: Vendors have years to get ready for these suggestions.... *[sic]*

Joel Andress: CMS and CDC are preparing to speak on the next steps for Medications next week, if there is an opportunity. Michelle was not able to join today, but we are very interested in pursuing some of the suggested opportunities to advance Medication data elements

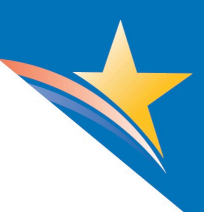
Grace Cordovano: <https://loinc.org/85231-9/>

Arien Malec: @Joel — in particular, aligning the Medication class with the data elements routinely available in interoperability (FHIR, CCDA, NCPDP SCRIPT) would do some good.

Arien Malec: There's a broader conversation about lists, etc.

## QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.



## Resources

[IS WG Webpage](#)

[IS WG – March 29, 2022 Meeting Webpage](#)

[IS WG – March 29, 2022 Meeting Agenda](#)

[IS WG – March 29, 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 to work on Charge 1 will be held on April 5, 2022. In response to a request from the co-chairs for feedback on the operations of the WG, members expressed that work was going well and that they were satisfied with the process.

The meeting was adjourned at 11:52 a.m. E.T.