



# Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

## Meeting Notes | January 25, 2022, 10:30 a.m. – 12:00 p.m. ET

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### Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) was to kick-off workgroup, including introductions, reviewing the workgroup charges, the draft of Version 3 of the United States Core Data for Interoperability (draft USCDI v3), and beginning to create a work plan for the IS WG. TF 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.	Workgroup Introductions
10:50 a.m.	IS WG Charges and Timelines
11:10 a.m.	Draft USCDI v3 Overview
11:40 a.m.	Workgroup Work Planning
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 10:30 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 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

Leslie Lenert, Medical University of South Carolina

Hung S. Luu, Children's Health

David McCallie, Individual



Clem McDonald, National Library of Medicine  
Aaron Miri, Baptist Health  
Mark Savage, Savage & Savage LLC  
Michelle Schreiber, Centers for Medicare & Medicaid Services  
Abby Sears, OCHIN  
Ram Sriram, National Institute of Standards and Technology

## **MEMBERS NOT IN ATTENDANCE**

Thomas Cantilina, Department of Defense  
Kensaku Kawamoto, University of Utah Health

## **ONC STAFF**

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

## **General Themes**

### **TOPIC: IS WG MEETING KICK-OFF**

The IS WG held a kick-off meeting for the newly formed workgroup.

## **Key Specific Points of Discussion**

### **TOPIC: OPENING REMARKS**

Steven Lane and Arien Malec, IS WG co-chairs, welcomed members and noted that some were new, while others were members of previous HITAC task forces and/or workgroups. Steven explained that this new task force combines the efforts of the prior United States Core Data for Interoperability Task Force (USCDI TF) and the Interoperability Standards Priorities Task Force (ISP TF), both of which had similar scopes of work. Steven reviewed the agenda for the meeting. Arien described how the charge of the previous two TFs would be combined and allow the WG to focus on setting a floor for the nation in terms of data and exchange.

### **TOPIC: WORKGROUP INTRODUCTIONS**

The co-chairs welcomed everyone and invited members to introduce themselves:

- Steven Lane is a practicing primary care family physician and informaticist at Sutter Health. His informatics focus has been on interoperability for 15 years. He is a member of the HITAC, is the chair of the Sequoia Project Board, the chair of the Carequality Steering Committee, and works on other local, regional and national initiatives to support interoperability.
- Arien Malec leads the research and development teams at Change Healthcare, which support large-scale information exchanges (clearinghouses, clinical exchanges/CommonWell, pharmacy adjudication). His background is in life sciences, including clinical trials, using informatics to advance oncology trials, and patient engagement/information exchange/interoperability.
- Kelly Aldrich is an informatics nurse specialist at Vanderbilt University, where she is Associate Professor, Director of Innovation in Informatics, and the Chief Clinical Officer at the Center for Medical Interoperability. She focuses on improving the seamless exchange of medical device information from a platform with a test certification lab. Previously, she was the CNIO at HCA Healthcare, where she focused on medical device interoperability and has served as a member of previous ONC FACAs.



- Hans Buitendijk is the Director of Interoperability Strategy at Cerner. He has focused on standards development, including various leadership roles at HL7, is a co-chair and participant in various workgroups and at CommonWell, and is on the board and steering committee of Carequality. He is also the chair of the Electronic Health Records Association (EHRA) and is the chair of their Standards and Interoperability Workgroup, focusing on progressing interoperability in the health information technology (HIT) space.
- Christina Caraballo is the Senior Director of Informatics at Healthcare Information and Management Systems Society (HIMSS), where she has strategic oversight of the Interoperability Showcase, the HIMSS Immunization Integration Program, and the Interoperability and Health Information Exchange Community, which is focused on social determinants of health (SDOH) and health information in general. She previously served as a member of the HITAC and as the co-chair of the USCDI TF.
- Grace Cordovano, CEO of Enlightening Results, is a board-certified patient advocate specializing in the oncology space, and guides her clients from point-of-diagnosis through treatment, survivorship, and end-of-life care planning. Her focus is on access to medical records and seamless actionable interoperable access. She has previously served as a member of the USCDI TF and is a member of the HIMSS Public Policy Committee, the HL7 Patient Empowerment Group, and the Protecting Privacy to Promote Interoperability (PP2PI) Workgroup.
- Steven Eichner is the Health IT Lead for the Texas Department of State Health Services, where he has been involved in collaborations supporting data exchange in both the public and private healthcare sectors. He has also focused on the integration of behavioral health and primary healthcare data, as well as on rare disease research and patient registries.
- Adi Gundlapalli is an informatician and infectious disease physician, as well as the Chief Public Health Informatics Officer at the Center for Surveillance, Epidemiology, and Laboratory Services at the Centers of Disease Control and Prevention (CDC). He provides strategic public health informatics leadership, supports public health data modernization efforts, and promotes interoperability and the use of data standards.
- Rajesh Godavarthi is the Associate Vice President of Technology and Interoperability at MCG Health (previously Milliman Care Guidelines). His background is in clinical decision support and interoperability strategy. He is a Workgroup for Electronic Data Interchange (WEDI) Board member and the HL7 Da Vinci Co-lead.
- Jim Jirjis leads the clinical informatics strategy for HCA Healthcare, where he is the Chief Health Information Officer of the Clinical Services Group. He is a member of the HITAC and has served on many of its workgroups and task forces.
- Leslie Lenert is the Assistant Provost for Data Science and Informatics and Professor of Internal Medicine in the Division of General Internal Medicine at the Medical University of South Carolina. He is also the Vice President and Chief Medical Officer of Health Sciences South Carolina, which is a statewide health information exchange and research collaborative. His research is focused on interoperability, Fast Healthcare Interoperability Resources (FHIR) population health applications, and accelerating translational informatics.
- Hung S. Luu is an Associate Professor of Pathology at the University of Texas Southwestern Medical Center and the Director of Clinical Pathology at Children's Health. He serves as the co-chair of the implementation committee for the Food and Drug Administration's (FDA) Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD) initiative and is also an active member of the informatics and standards committees at the College of American Pathologists.
- David McCallie is currently retired from the industry but recently concluded a nearly 30-year career in informatics at Cerner, where he focused on product development and interoperability. Previously, he was at Boston Children's Hospital, where he completed his medical training and studied neurology. He was an original member of the HIT standards committee, a co-founder of CommonWell, and a member of the Interoperability Standards Priorities Taskforce.



- Clem McDonald is the Chief Health Data Standards Officer of the National Library of Medicine (NLM), where he has directed the building of many tools. Prior to coming to NLM, Dr. McDonald served as a distinguished Professor of Medicine and of Medical Informatics at the Indiana University School of Medicine and the Director of the Regenstrief Institute for Health Care Questionnaire. His career has spanned many decades, and he is a longtime member of the HITAC and a participant on many of its workgroups and task forces.
- Aaron Miri is the Senior Vice President and Chief Digital & Information Officer at Baptist Health. He is the current co-chair of the HITAC and has served on many of its task forces and workgroups. He is also on the board of CommonWell.
- Mark Savage is the Director of Digital Health Policy at Savage and Savage LLC and previously served on the USCDI TF. He is the policy lead for the Gravity Project, where he has focused on integrating SDOH data for nationwide, interoperable health information exchange across the health and human services ecosystems, beginning with consensus-driven SDOH standards development and FHIR-enabled interoperability.
- Michelle Schreiber is the Deputy Director of the Center for Clinical Standards and the Quality (CCSQ) and the Director of the Quality Measurement and Value-based Incentives Group (QMVIG) at the Centers for Medicare and Medicaid Services (CMS). She has a background as a general internal medicine physician and has implemented many electronic medical record systems. She is a member of the HITAC and has served previously on the USCDI TF. At CMS, she has focused on moving to fully digital quality measures.
- Abby Sears is the President and Chief Executive Officer at OCHIN (previously Oregon Community Health Information Network), where she focuses on software as a service, research, hosting of Epic across the US, the movement of data from a health equity/more culturally competent standpoint. She is a member of the HITAC and has served on many of its task forces and workgroups. She is also involved in HL7, the Gravity Project, the National Quality Forum (NQF), the Sequoia Project, and others.
- Ram Sriram is the chief of the Software and Systems Division, Information Technology Laboratory, at the National Institute of Standards and Technology (NIST). He also serves as the manager of the NIST's Health IT Program, where he focuses on clinical informatics, bioinformatics, developing tools and techniques for promoting interoperability across the enterprise, R&D in and supporting the development of security protocols, and the ontologies and semantics of representing information. He is a member of the HITAC and works on interoperability at his wife's small medical practice.

## TOPIC: IS WG CHARGES AND TIMELINE

Steven and Arien reviewed the charges, potential specific areas of focus, and the timeline for the IS WG, all of which were detailed on slides #8 through #11 in the [WG's presentation slides for meeting #1](#). The co-chairs described the areas of focus for this iteration of the WG, which runs through June 2022, and invited WG members to submit feedback. The charges 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:
    2. 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.

#### DISCUSSION:

- Steven Lane thanked Hung Luu for joining the WG and explained that he looks forward to addressing the FDA's SHIELD initiative during work on the WG's Charge 2.
- Arien and Christina strategized how the WG could provide feedback on the charges. Arien suggested that the WG focus on Charge 1 first, while potentially creating a sub-workgroup to begin to focus on the ISA-related topics in Charge 2.
- Members inquired if small sub-committees could be formed within the WG as soon as possible to address the additional topics/areas of focus.

#### TOPIC: DRAFT USCDI V3 OVERVIEW

Al Taylor explained that he continues to serve as the technical lead from ONC on USCDI-related work. At the request of IS WG members, he highlighted the impact of the USCDI throughout his presentation. He provided an overview of the core principles of the USCDI, which were detailed on [slide #13 in the presentation materials](#).

Then, he described the USCDI v3 prioritization criteria, including the prioritization criteria from Version 2 of the USCDI (USCDI v2) that will continue to be used for USCDI v3. These were detailed on slide #14. He explained that ONC wants to promote an incremental adoption of the USCDI with each version incorporating modest changes from the prior version because these are voluntary changes for systems. He stated that, while there may be many mature, high-quality data elements that could be added, the WG will assess how to best keep changes between USCDI versions at a modest level. All the prioritization criteria were used to assess Level 2 data elements and classes for inclusion in USCDI v3.



Information on submissions was detailed in slide #15, and the two new data classes and 20 data elements introduced in draft USCDI v3 were included on slide #16. AI described how classes and elements were created and explained how the new items were highlighted in terms of equity-based factors, how underserved communities and public health can be better served, additional USCDI needs, and items that are already being exchanged by certified health IT. He explained how data classes and elements were rearranged within draft USCDI v3, which was included on slide #17. AI described how ONC added more information to the definitions for some data elements, including value set information under the applicable vocabulary set standards category (useful for developers and will likely be part of the test data in the certification process). AI provided background on the new elements/classes and rearranged items, all of which were detailed in slides #18 through #22. He explained that the value sets are finite sets of terms that are carried within the standards listed; however, ONC would like IS WG members to provide input on the appropriateness of these value sets. Also, ONC intends to update applicable vocabulary standards to their most recent published versions for the final published USCDI v3.

AI described the timeline for the USCDI version update process, which was included on slide #24. He stated that the plan is to publish the final version USCDI v3 in July 2022 and described how ONC's timeline has shifted/been delayed.

#### DISCUSSION:

- Rajesh inquired how the prioritization criteria intersect with the contents of the HITAC Annual Reports.
  - AI responded that the recommendations for priorities from the previous version of the Annual Report were adopted and reflected in draft USCDI v3.
- AI responded to comments from the chat by explaining that previous versions of the USCDI are not a rule and that subsequent version updates can be voluntarily adopted by health IT developers providing updates to their customers. He explained that ONC is currently using its Standards Version Advancement Process (SVAP) to consider USCDI v2, and, pending approval via SVAP, systems would be able to make updates using USCDI v2 soon. Only USCDI v1 is required for certified health IT at this point, until such time as a newer version of USCDI is adopted through the rulemaking process.
- Arien and Grace asked AI to comment on ties between the USCDI v3 (current and future work, impacts) and Information Blocking.
  - AI explained that this is a complicated topic and stated that, under most circumstances, blocking information exchange is subject to penalties for blocking. There are exceptions, but the amount of information that would constitute blocking only includes what was covered in USCDI v1. This will change in October 2022, when any information that is part of the electronic Designated Records Set and managed by a system will be subject to Information Blocking provisions (much broader than USCDI v1).
- Mark inquired how the certification for FHIR v4 APIs at the end of 2022 would impact ONC's process for the USCDI timeline.
  - AI explained that the FHIR API standard and requirements will apply only to USCDI v1.
  - Arien suggested that the workgroup comment on future policy levers and to not get confused by the current mismatch.
- Clem encouraged the IS WG and ONC not to be so shy about recommending more items for inclusion in USCDI (as opposed to the more incremental approach advocated by ONC). He highlighted the need for the use of common codes. He thanked ONC for the inclusion of the new classes.
  - AI emphasized that the regulatory impact of new requirements is felt across the health IT ecosystem, and the more incremental approach is meant to encourage greater voluntary adoption by systems.



- Arien reminded members that the WG may submit comments on policy levers and recommendations for changes to the both the floor and the ceiling for interoperable data and associated standards.
- Clem inquired how FHIR regulations/criteria and the USCDI interact, and AI responded that the FHIR criteria and content must be at least partially defined by USCDI. FHIR based APIs constitute one means by which the data elements defined in USCDI are exchanged, so changes to USCDI versions would need to be incorporated into the FHIR US Core Implementation Guides.
- Clem asked how the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) survey instrument would fit into this new draft version, and AI responded that PRAPARE is one of many assessment instruments that are part of the SDOH Assessment data element, first introduced in USCDI v2.
- Grace asked for clarification around the public comment process, noting that commenting on the draft version of the USCDI is a separate process from submitting suggestions to the ONC New Data Element and Class (ONDEC) Submission System. She stated that the distinction between these processes is not clear, and AI responded that ONC attempted to make this process clearer within the published bulletin and document. ONC is looking for feedback directly on the USCDI website.

## Action Items and Next Steps

IS WG members will be asked to capture their thoughts and recommendations between meetings in a Google doc 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](mailto:onc-hitac@accelsolutionsllc.com) to be set up with access to the document. A link will be sent once access is established.

The IS WG's first area of focus and discussion (month of February) will be:

- Charge 1a: Evaluate new data classes and elements in [Draft USCDI v3](#) Including data class and element names, definitions, representative value sets.
- Consider and come prepared to suggest any indicated changes to these data classes and elements.
  - Should some of these not be included and why?
  - Are there significant barriers to implementation that warrant removing any of these data elements from consideration?
- Specific ONC requested topics:
  - Sex/Gender – presentation scheduled for Feb 8 (with Gender Harmony presenting)
  - 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 Workgroup 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

Al Taylor: Is this the beginning of “Today, a Florida man...” joke?

Arien Malec: I totally didn’t think about making that joke.

Steven Eichner: I would like to be engaged in discussions regarding potential certification of systems used by public health.

Steven Eichner: There may be a need for similar task forces on other aspects.

Hans Buitendijk: From a disclosure perspective, I am one of the co-lead of the HL7 LIVD project under Orders & Observations Workgroup to express the recommended mappings by device manufactures for both test and result encoding between IVD Test/Result codes and LOINC/SNOMED using FHIR based expressions.

Steven Eichner: One of the underlying currents we should probably consider is how to operationalize standards, such as transitioning from what is to US@. Is there a vision for how to operationalize transition? Would it be live ICD-10, in terms of a single target date for national change?

Arien Malec: Hans - that’s exciting -- we certainly have a powerhouse here on SHIELD — we might want to go back to the original set of recommendations to discuss how to get real multi-lateral exchange of laboratory orders/results.

Arien Malec: @Eichner — good point - we often provide comment on policy levers that ONC and other actors might use to advance interoperability.

Hans Buitendijk: Agreed. As HL7 Orders & Observations (O&O) Co-Chair I also am very close (as Clem can attest) to all the Lab orders & results standards (v2 and FHIR, plus as needed in C-CDA) as O&O owns that space for HL7.

Steven Lane: It is important to appreciate that this is an iterative process and that USCDI is anticipated to continue to make progress year after year. While it is tempting to make rapid leaps forward, the measured/modest approach supported by ONC does move the industry





forward and we have yet to see how this plays out in the real world through the SVAP and reference by rule making.

Steven Eichner: On lab orders/results/public health: One of the concepts that may be worth exploring is changing the model used to connect to public health and other data resources, with a goal of reducing the number of systems that need to be modified while improving the quality/completeness/timeliness of data submission to public health as well as delivering results to a patient's regular care team. I've been working on a draft model that may help address some of those needs/wants.

Grace Cordovano: Steven/Arien, can you clarify how the October 6, 2022 Information Blocking deadline applies to or shapes the work we do here?

Hans Buitendijk: @AI - a future new certification update through rule making could require a new USCDI version (and/or USCDI + variant) floor, correct? But no dates, nothing on a defined horizon yet, just process flow.

Hans Buitendijk: For certification, specific FHIR and C-CDA versions are the standards that support USCDI v1 that one must demonstrate support for. That is not an exact 1:1 match in that FHIR and C-CDA actually support/require some data that are not explicitly listed in USCDI v1.

Steven Eichner: I've lowered my hand. I've noticed that one of the new criteria are to "address the needs of underserved stakeholders." Should this be interpreted as including their interests? How have available vocabularies been developed? Who has provided input?

Steven Lane: Love the icons!

Steven Lane: Members of the prior USCDI TF suggested adding items included in HIT Certification to align USCDI in this manner.

Steven Lane: Anyone with domain expertise is welcome to recommend vocabulary standards and/or value sets to apply to those data elements where none has been specified.

Grace Cordovano: Great to see Related Person's Name & Relationships represented as this is a major unmet need, causing significant barriers to care coordination and communication, especially in light of COVID19 No Visitor Policies at health systems and providers practices.

Arien Malec: I'm confused by the difference between Tribal Affiliation and the CDC vocabulary standard included in the USCDI definition of race/ethnicity.

Steven Eichner: The "Disability Status" components appear to reflect functional abilities. Are these the same as status? At least one of the disability status elements combines physical and mental health topics. This *[sic]* may need to be revisited.

Mark Savage: @Grace +1 Family and community caregivers!

Steven Lane: We had a lively discussion in last year's Taskforce regarding the challenges with terminology related to disability, functional status.

Mark Savage: Steve/Arien, would be good to learn if ONC's selections for draft v3 reflect some thinking or decisions on that lively debate.

Christina Caraballo: Since adopting new versions of USCDI is voluntary, the incremental approach could potentially stall progress. While it is important to consider incremental updates for broad implementation, we should add to USCDI as data class/elements meet the criteria. We



may consider a tagging system for tiered adoption if there are concerns that the industry will be overburdened. For example, when a new version is tied to regs, USCDI can have tags attached to data elements that indicate how long industry has to adopt them.

Arien Malec: @clem — my understanding is that FHIR loosely couples vocabulary standards, but that the implementation guide for FHIR aligned with USCDI makes requirements for vocabulary standards also aligned.

Mark Savage: The USCDI TF also had a long, vigorous discussion about how critical national use cases require more than an incremental, modest approach. And we made recommendations to HITAC accordingly, and HITAC made those recommendations to the National Coordinator. Looks like more vigorous conversation to come, keeping our eye on national priorities and policies to meet them.

Hans Buitendijk: FHIR Core (base standard) loosely links/binds to vocabulary as it is global, while FHIR US Core more strongly binds to vocabulary for US. One of the challenges for FHIR US Core will be the various layers/focus areas that USCDI + FHIR Accelerator topics will further highlight where there are variant areas of binding, but need to fit together.

Steven Eichner: There may be some value in touching on USCDI prime or other future efforts, especially as it relates to ISA discussions.

Kelly Aldrich: Thank you.

## **QUESTIONS AND COMMENTS RECEIVED VIA EMAIL**

There were no public comments received via email.

## **Resources**

[IS WG Webpage](#)

[IS WG – January 25, 2022 Meeting Webpage](#)

[IS WG – January 25, 2022 Meeting Agenda](#)

[IS WG – January 25, 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.