

Health Information Technology Advisory Committee

Interoperability Standards Workgroup 2023 Virtual Meeting

Meeting Notes | February 22, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) was to review workgroup charges and Draft United States Core Data for Interoperability Version 4 (USCDI v4) data elements. The IS WG discussed these topics and provided feedback. There was robust discussion via the chat feature in Zoom Webinar.

Agenda

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| 10:30 AM | Call to Order/Roll Call |
| 10:35 AM | IS WG Charge |
| 10:40 AM | Comments and Recommendations – New Draft USCDI v4 data elements |
| 11:45 AM | IS WG Workplan and Timeline |
| 11:55 AM | Public Comment |
| 12:00 PM | 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 AM.

Roll Call

Members in Attendance

Sarah DeSilvey, Gravity Project, Larner College of Medicine at the University of Vermont, Co-Chair
Naresh Sundar Rajan, CyncHealth, Co-Chair
Pooja Babbar, Point-of-Care Partners
Shila Blend, North Dakota Health Information Network
Ricky Bloomfield, Apple
Hans Buitendijk, Oracle Health
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Raj Dash, College of American Pathologists
Steven Eichner, Texas Department of State Health Services
Nedra Garrett, Centers for Disease Control and Prevention
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Bryant Thomas Karras, Washington State Department of Health



Steven Lane, Health Gorilla
Hung Luu, Children's Health
Anna McCollister, Individual
Deven McGraw, Invitae Corporation
Kikelomo Adedayo Oshunkentan, Pegasystems
Shelly Spiro, Pharmacy HIT Collaborative
Ram Sriram, National Institute of Standards and Technology

Members Not in Attendance

Meg Marshall, Department of Veterans Health Affairs
Clem McDonald, National Library of Medicine
Aaron Miri, Baptist Health
Aaron Neinstein, UCSF Health
Mark Savage, Savage & Savage LLC
Michelle Schreiber, Centers for Medicare and Medicaid Services

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Al Taylor, USCDI Lead, ONC

Key Points of Discussion

Opening Remarks

IS WG co-chairs, Sarah DeSilvey and Naresh Sundar Rajan, welcomed attendees. Sarah reviewed the meeting agenda detailed in the [February 22, 2023, meeting presentation slides](#).

IS WG Charge

Sarah reviewed the IS WG Charge. The charge includes:

- Overarching charge: Review and provide recommendations on the Draft USCDI v4.
- Specific charge:
 - Due to the HITAC by April 12, 2023:
 1. Evaluate Draft USCDI v4 and provide HITAC with recommendations for:
 - a. New data classes and elements from Draft USCDI v4.
 - b. Level 2 data classes and elements not included in Draft USCDI v4.

Discussion:

No comments were received from IS WG members.



Comments and Recommendations – New Draft USCDI v4 data elements

Sarah DeSilvey presented the IS WG Charge, detailed in presentation slides. This presentation included a tentative schedule review of Draft USCDI v4 new data classes and elements. Al Taylor then presented the IS WG disposition working google document.

IS WG members reviewed the google document and provided feedback. The following data elements were discussed: Medical Instructions, Medication Adherence, Treatment Intervention Preference and Care Experience Preference. IS WG members agreed to revisit these data elements given a need for discussion with Subject Matter Experts (SMEs). A subset of IS WG members will be convened to discuss Medication Instructions and Medication Adherence before the next IS WG meeting.

Discussion:

- Hans Buitendijk requested a process for IS WG members to comment on data elements addressed in previous IS WG meetings.
 - Comments aligning with the IS WG consensus can be inserted in the working google document.
 - Comments not in alignment with the IS WG consensus should be elevated via email to IS WG Co-Chairs and Al Taylor.
- IS WG members discussed the following data element: Medication Instructions.
 - Hans expressed a need for clarity regarding Medication Instructions and explained that the scope and complexity of this data element depend on interpretation and intent. Hans noted If the intent of this data element is implementation by the Pharmacist eCare Plan there is added complexity.
 - Shelly Spiro explained that her organization has been working with NCPDP to codify Medication Instructions in LOINC. There are implications for the use of this data element in electronic prescribing and Electronic Health Record (EHR) medication administration records in hospital and long-term post-acute care settings. Shelly noted the inconsistent use of Medication Instructions with text-based or proprietary coding. Shelly also noted the Pharmacist eCare Plan's use of Medication Instructions.
 - Steven Lane discussed the value of Medication Instructions from a clinical perspective and referenced his comments in the working google document. Steven Lane inquired if this data element includes Codified Sig data elements.
 - Al noted that ONC recognizes Structured and Codified Sig as an existing standard and not required by ONC's certification program. ONC does not intend to limit this data element to a single standard or instruction.
 - Ricky Bloomfield noted the data element definition includes package instructions for over-the-counter medications. Ricky inquired if the data element includes medication warnings. Ricky suggested that the IS WG clarify the scope of this data element and noted the importance of using Free Text Sig. Al suggested revising the Medication Instruction definition and examples. Al suggested a possible ISWG recommendation to replace "package instructions" with "dosing instructions" in the data element definition currently in Draft USCDI v4.
 - Hans requested confirmation the data element includes Free Text/Structured Sig and excludes patient instructions.
 - Al explained the intent of this data element is to convey how a medication should be taken by quantity and route (and other elements). Al then explained that Medication Instruction could be paired with the Medication Adherence data element.



- Sarah noted the need to revise data element definitions to clearly detail what is being discussed by the IS WG.
- Shelly discussed regulatory drivers for Medication Instructions, its linkage to structured product labeling and its linkage to Structured and Codified Sig. Shelly also explained her organization's use of free text and proprietary text-based codes. Shelly suggested inviting SMEs from the Pharmacy Workgroup to obtain input regarding the Electronic Medication Administration Record (eMAR).
- Grace Cordovano inquired if this data element includes patient-available medication instructions.
- Shelly explained that regulatory requirements are in place for pharmacists to provide common medication language to patients. Common language can incorporate structured product and proprietary language. The Medication Instruction data element is focused on codifying language for communication between entities and ensuring text-based information will not be interfered with or misinterpreted. Grace suggested including Shelly's data element explanation in the working google document.
- Sarah summarized IS WG viewpoints. There is general support for this data element utilizing Sig and free text as common methods for documentation. There is also support for the exploration of codified text elements.
- IS WG members suggested inviting SME Scott Robertson to attend future IS WG meetings and discuss this data element.
- IS WG members agreed to convene a small working session to discuss this data element.
- IS WG members agreed to revisit the topic of Medication Instructions given the need for discussion with key stakeholders at a future IS WG meeting.
- IS WG members discussed the following data element: Medication Adherence.
 - Shelly noted that Medication Adherence is a priority topic in pharmacies and is related to payer quality measures. Shelly and others in her field look at medication adherence to ensure patients understand and utilize medications. SNOMED codes and value sets in the Value Set Authority Center (VSAC) have been created to document medication adherence.
 - Pooja Babbrah agreed with Shelly's comments. Pooja expressed concern that this data element lacks clarity and suggested determining its intent to educate patients vs. pharmacist conversations with patients.
 - Hans agreed with Pooja's comments. IS WG members need to ensure clarity of scope for this data element. Is this data element meant for documentation by the clinician or patient adherence views? Additional work is needed before the IS WG can reach a consensus on a USCDI recommendation.
 - Anna McCollister agreed that the data element's intent and use are not clear. From a patient's perspective, Anna explained that the term adherence can act as an emotional trigger without enough clarity and context. Some factors, out of patient control, contribute to a lack of medication adherence and should not result in negative adherence perspectives.
 - Ricky agreed with IS WG member comments. Ricky suggested clarifying whether Medication Adherence is being collected in a home or clinical setting. Ricky suggested the incorporation of general recommendations, which include specific scenarios.
 - Al explained that ONC's intent of this data element is to convey information about whether the patient is using the medication as understood by an EHR or a provider. This data element should represent patient-reported data, not dispensed or prescribed data.
 - Grace stated the intent of Medication Adherence should not lead to opportunities of patient stigmatizing especially if the lack of adherence is due to reasons outside of patients' control.




AI agreed with Grace and explained that the use of this data element can lead to a new approach to address adherence, including “reason for non-adherence”.

- Shelly noted that reasons for medication discontinuation are being used by the Pharmacracy eCare Plan and in the independent pharmacy setting. Reasons for discontinued medication have been built within VSAC and SNOMED. Shelly noted there are different tools available to ensure medication adherence in a variety of settings.
- Pooja suggested changing the name of this data element.
- AI noted that ONC is open to revisions for this data element’s name.
- Sarah suggested inviting SME Scott Robertson to attend a future IS WG meeting and discuss this data element.
- Steven Lane expressed support in recommending this data element at a high level and reminded IS WG members of the need for this data element. Once implemented in USCDI, individuals can work to improve Medication Adherence.
- Grace discussed the IS WG’s opportunity to determine the best intent and value of Medication Adherence. Grace suggested incorporating other valued aspects, such as social determinants of health factors and quality of life related to patient medication adherence.
- IS WG members agreed to convene a small working session to discuss this data element prior to the next IS WG meeting.
- IS WG members agreed to revisit the topic of Medication Adherence, given the need for discussion with key stakeholders.
- IS WG members discussed the following data element: Treatment Intervention Preference and Care Experience Preference.
 - Sarah requested a brief IS WG member conversation regarding these data elements and suggestions for SMEs.
 - Shila Blend expressed concern that the working google document includes comments in this section that are related to other data elements.
 - Steven inquired about ONC’s logic for moving specific level 2 data elements forward in Draft USCDI v4. AI explained ONC’s published process to adopt new data elements based on public submissions. AI addressed IS WG comments in the working google document.
 - Hans noted these data elements point to larger implementation guides that are more comprehensive than the singular data elements. Hans inquired what the area of focus is for USCDI v4, specific data elements or larger concepts? Hans explained that Treatment Intervention Preferences has become its own data class. Hans explained the need for added clarity of USCDI scope as it relates to this data element.
 - Shelly shared, utilizing her experience in a long term post-acute care setting, this data element relates to transitions of care. Shelly suggested proposing a data class in relation to transitions of care. Treatment and Intervention Preferences are important in the transition of care process. Shelly recommended inviting SMEs Dr. Terry O’Malley and Dr. Holly Miller to discuss transitions of care.

IS WG Workplan and Timeline

Sarah DeSilvey reviewed the upcoming IS WG meeting and Draft USCDI v4 review schedule. To allow for final recommendation review at the April HITAC meeting, IS WG comments should be finalized by the middle to end of March.



Sarah encouraged IS WG members to suggest stakeholders for inclusion into USCDI v4 discussions at the bottom of the disposition google document. Hans Buitendijk suggested a review of IS WG recommendations by the HL7 group working to move forward USCDI data elements in FHIR.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments:

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No public comments were received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the Interoperability Standards Workgroup! We will be starting soon. Please remember to tag "Everyone" when using Zoom chat if you want all to see your message.

Hans Buitendijk: So am I hearing both free text patient instructions and structured SIG? Not FHIR PHCP IG, although that seemed implied in the submission?

Grace Cordovano: +1 Ricky

Hans Buitendijk: @Ricky Do you consider .patientInstruction = free text SIG?

Hans Buitendijk: Free text dosage instructions are already Must Support.

Grace Cordovano: Can someone please clarify, is Structured and Codified Sig also information geared for patients or only between clinicians?

Hans Buitendijk: From a standards/implementation perspective they are distinctively different, although no disagreement they will relate in some way.


Hans Buitendijk: And then in MedicationStatement (related to Medication Adherence) the patient perspective can be addressed.

Steven Lane: I think that we need to separately recommend and prioritize the various data elements of interest - free text sig (make required), specified discrete sig elements, patient specified 'how they are taking', OTC package instructions, etc.

Scott Robertson: structured and codified instructions represent the instructions to the patient in a machine-computable form. Patient's don't "need" the structured content, but the meaning of the free-text the patient sees and the coded content must agree

Sarah DeSilvey: Correct, so it seems we have "directions for use" as one thing, the sig. and "patient report of use", what the patient is doing. Both with capacity for free and structured data. and different from both, "adherence: taking as directed, not taking as directed, not taking"

Raj Dash (CAP): SNOMED CT is used to represent Medical Condition in Structured Product Labeling in order to facilitate informed decision-making and support (not LOINC). <https://www.fda.gov/industry/structured-product-labeling-resources/medical-condition>



Patrice Kuppe: From the NCPDP Structured and Codified SIG Guide: Included in the Structured and Codified Sig Format are elements, fields and values that are directly related to the prescriber's instructions for use.

Hans Buitendijk: Plus there is a .patientInstruction attribute which specifically can add context for patient.

Steven Lane: Yes, @Ricky. I support including free text SIG in USCDI at a minimum, recalling that adding a data element to USCDI does NOT require that it be collected, but rather says that IF it exists within the source system it shall be exchanged once the applicable USCDI version is required.

Scott Robertson: yes, there is a patient instruction (text) field

Kim Boyd: yes to codification and regulatory drivers to adopt and use

Sarah DeSilvey: + 1 Steven

Scott Robertson: codified information is seldom useful for any human (patient or prescriber)

Hans Buitendijk: @Scott Robertson - What data of the fully structured SIG is not yet supported in FHIR US Core MedicationRequest profile? Is that documented? That would help clarify what gap is intended to be addressed specifically.

Pooja Babbrah: My apologies for being late. This is pooja babbrah. I'm on the call now

Raj Dash (CAP): FDA requires SNOMED CT for structured product labeling...

Scott Robertson: mapping between StructuredSig and FHIR has not been done. I believe there is "more" in StructuredSig, being involved in both.

Scott Robertson: To clarify, most of the coded elements in StructuredSig are SNOMED (or FMT). LOINC is used when appropriate. I can provide details if desired

Pooja Babbrah: I ageee. I included Scott as a SME for the next meeting

Hans Buitendijk: +1 Pooja

Grace Cordovano: Are SDoH and barriers to access noted in this element?

Sarah DeSilvey: That is a good thought grace, at Gravity we worked with NCHS and friends to create ICD codes to specify when financial concerns were the driver for medication or regimen non adherence. I do know that social drivers are centered in the eCare Plan work.

Kim Boyd: yes Shelly and Pooja... also.. does the patient metabolize appropriately.. is precision medicine a part of this too

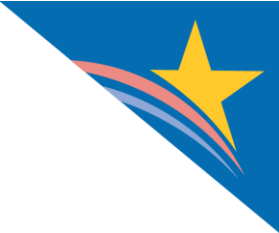
Shila Blend: Will medication adherence be how the patient takes it or a Y/N saying they adhere

Pooja Babbrah: That is a great point Anna

Hans Buitendijk: @Ricky - and add MedicationAdministration where clinician is involved in recording actual use (taken, refused, delayed, etc.) Which depending on setting is or is not part of the discussion.

Shila Blend: Should there be a separate element for reason for not adhering

Sarah DeSilvey: + 1 Ricky



Hans Buitendijk: The challenge is that information about adherence is can still be very wide or narrow that may involve more than a single field with yes or no on the general prescription or on each administration, or something in-between. While patient provided, does that imply and then transcribed by the provider, or as entered by the patient. We need to be more specific on intent.

Shila Blend: Agree Hans. It is quite a challenge

Scott Robertson: there are systems (devices) that monitor when a medication is taken. this would be more precise than patient reported, but is not widely in use

Pooja Babbrah: If we do move this data element forward I think it's important to include the additional data element of why the patient may not be taking their med that Shelly just spoke about

Sarah DeSilvey: +1 Pooja

Kim Boyd: *2 pooja

Grace Cordovano: +1 Pooja

Shila Blend: +1 Pooja

Scott Robertson: "adherence" is the more recent term used in clinical practice

Scott Robertson: "compliance" was a previous term

Grace Cordovano: The actual question is "taken as prescribed"

Steven Lane: Or "taken at all"

Sarah DeSilvey: This is why I wonder if we might just be talking about different facets of adherence: medication adherence status (taking, not taking), and "medication non-adherence reason"

Scott Robertson: the question is "how do you take your medication". the analysis is adherence/compliance

Hans Buitendijk: Adherence can support the level of specificity available where we need to focus on what level of specificity for patient provided adherence is providing a good start.

Steven Lane: Also, I agree that "adherence" is a more patient-centric and less judgmental term than "compliance".

Pooja Babbrah: Thank you Steven for that voice of reason

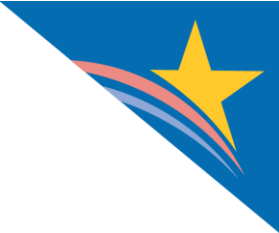
Hans Buitendijk: Moving the full FHIR PHCP IG forward would be substantially more than the very specific discussion that seems to emerge.

Steven Lane: Our opportunity to "push the envelope" is to specify additional Level 2 data elements that could add context and make the inclusion of Adherence more valuable.

Grace Cordovano: +1 Steven

Scott Robertson: I am available for future meetings

Shila Blend: Instead of adherence, could we consider any barriers to adherence?



Albert Taylor: There is a Level 2 data element called "Negation Rationale" which captures reasons not taken/given. The WG could recommend advance that data element to USCDI v4.

Hans Buitendijk: It is clear that "adherence" is not a single element concept, but can range from 1-2 fields of interest to start, to a spectrum or elements across dispense, administration and statements to achieve a comprehensive insight on adherence.

Steven Lane: @Shila - Barriers to or explanation of reasons for the degree of Adherence would provide very helpful context, but are different than the degree of adherence itself.

Shila Blend: @Steven I understand that which is why we should look at another element in addition to clarifying this one

Steven Lane: +1 @Shila - "in addition to", not "instead of". :-)

Pooja Babbrah: +1 Steven.

Albert Taylor: @Hans it might be helpful to think of this data element as a "category" of patient goals that address a particular aspect of care. Similar to how ONC added SDOH Goals as a separate category of patient goal.

Sarah DeSilvey: Preferences in care planning are often preferred paths to goals. Goal= dying gracefully, preference= do not intubate. Goal= food security, preference = leveraging federal nutrition support programs.

Pooja Babbrah: Is anyone familiar with the work being done at PACIO around this?

Pooja Babbrah: Thanks sarah

Christina Caraballo: Agree to bring in Terry and Holly.

Steven Lane: +2 to inviting Terry and Holly

Hans Buitendijk: @Pooja: Happy to help.

Pooja Babbrah: Thanks Hans

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Resources

[IS WG Webpage](#)

[IS WG – February 22, 2023, Meeting Webpage](#)

[HITAC Calendar Webpage](#)

Adjournment

The meeting was adjourned at 11:59 AM.