Interoperability Standards Workgroup Recommendations on Draft USCDI Version 5 - HITAC Vote

Sarah DeSilvey, Workgroup Co-Chair
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April 11, 2024

Agenda

- IS WG Roster

- IS WG Charge

- IS WG Workplan

- IS WG Draft USCDI v5 Recommendations

- Level 2 Data Elements Not Included in Draft USCDI v5 Recommendations

Interoperability Standards Workgroup Roster

Name	Organization	Name	Organization
Sarah DeSilvey* (Co-Chair)	Gravity Project	**Steven Eichner* (Co-Chair)**	Texas Department of State Health Services
Pooja Babbrah	Point-of-Care Partners	Steven Lane	Health Gorilla
Shila Blend*	North Dakota Health Information Network	Hung Luu*	Children's Health
Ricky Bloomfield	Apple	Anna McCollister*	Individual
Medell Briggs-Malonson*	UCLA Health	Katrina Miller Parrish*	Humana Health Insurance
Hans Buitendijk*	Oracle Health	Alex Mugge**	Centers for Medicare and Medicaid Services
Keith Campbell**	Food and Drug Administration	Aaron Neinstein*	Notable
Christina Caraballo	HIMSS	Kikelomo Oshunkentan*	Pegasystems
Grace Cordovano	Enlightening Results	Rochelle Prosser*	Orchid Healthcare Solutions
Raj Dash	College of American Pathologists	Mark Savage	Savage & Savage LLC
Derek De Young*	Epic	Fillipe Southerland*	Yardi Systems, Inc.
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Shelly Spiro	Pharmacy Health Information Technology Collaborative
Hannah Galvin*	Cambridge Health Alliance	Zeynep Sumer-King*	NewYork-Presbyterian
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Naresh Sundar Rajan*	CyncHealth
Jim Jirjis**	Centers for Disease Control and Prevention		

* HITAC Member
** HITAC Federal Representative

Interoperability Standards Workgroup Charge

Overarching charge: Review and provide recommendations on the Draft USCDI Version 5

Specific charge: **Due**

Evaluate Draft USCDI v5 and provide ONC with recommendations for: **April 11, 2024**

a. New data classes and elements from Draft USCDI v5 that should be considered for the final USCDI v5 release.
b. Level 2 data classes and elements not included in Draft USCDI v5 that should be considered for the final USCDI v5 release.

New Data Classes and Elements from Draft USCDI v5

Clinical Notes
- Emergency Department Note
- Operative Note

Immunizations
- Lot Number

Laboratory
- Test Kit Unique Device Identifier

Medications
- Route

Observations (New Class)
- Advance Directive Observation
- Sex Parameter for Clinical Use

Orders (New Class)
- Orders

Patient Demographics/Information
- Interpreter Needed
- Pronoun
- Name to Use

Provenance
- Author
- Author Role

Charge (b) – Level 2 elements not included in Draft USCDI v5: Elements Reviewed by IS WG

Data Class	Data Element
Patient Summary and Plan	Care Plan
Health Status Assessment	Health Literacy Status
Laboratory	Specimen Collection Date/Time
Allergies and Intolerances	Substance (Food)
Family Health History	Family Health History
Patient Demographics/Information	Identifier
Patient Demographics/Information	Patient Identifier Type

Charge (b) – Level 2 elements not included in Draft USCDI v5: Elements Reviewed by IS WG

List current as of 2/27/24

Data Class	Data Element
Health Insurance Information	Coverage Period
	Policy Number
	Medicare Patient Identifier
	Payer Name
	Plan Name
	Plan Identifier
	Group Name
Clinical Notes	Maternal SDOH Note
Medications	Medication Administration
Medications	Medication Prescribed Code

Charge (b) – Level 2 elements not included in Draft USCDI v5: Elements Reviewed by IS WG

Data Class	Data Element
Medical Devices	Device Used
Provenance	Signature
Immunizations	Immunization Status
Immunizations	Vaccination Event Record Type
Goals and Preferences	Healthcare Agent
Orders	Portable Medical Orders
Advance Directives	
Facility Information	Facility Address

Other Data Elements Reviewed by IS WG

Data Class	Data Element
Patient Demographics/Information	Sex
Patient Demographics/Information	Gender Identity
Patient Summary and Plan	Assessment and Plan of Treatment
Goals and Preferences	Healthcare Agent

Key Workgroup Meetings and Areas of Focus

IS WG Meeting	Areas of Focus
February 6, 2024	New Draft USCDI v5 data elements
February 13, 2024	New Draft USCDI v5 data elements
February 20, 2024	Sex Parameter for Clinical Use, Pronoun, Name to Use
February 27, 2024	Advance Directive Observation, Orders
March 5, 2024	Care Plan*
March 19, 2024	Level 2 elements not included in Draft USCDI v5*
March 26, 2024	Author, Author Role, Advance Directive Observation
April 2, 2024	Finalize ISWG Recommendation Letter to HITAC
April 9, 2024	Finalize ISWG Recommendation Letter to HITAC

*Data elements not included in Draft USCDI v5

SME Presentations

February 20, 2024	Sex Parameter for Clinical Use	Carol Macumber, Clinical Architecture
	Pronoun	Rob McClure, MD Partners
	Name to Use	
February 27, 2024	Advance Directive Observation	Maria Moen, MyDirective
	Orders	
March 5, 2024	Care Plan	Jenna Norton, NIH/NIDDK
		Arlene Bierman, AHRQ
		Liz Palena-Hall, CMS
		Evelyn Gallego, EMI Advisors

IS WG Recommendations Report Format

Background

Charge (a) Draft USCDI v5 data element recommendations

Charge (b) Level 2 data element recommendations

Recommendations for Future Consideration (Not Draft v5 or Level 2 data elements)
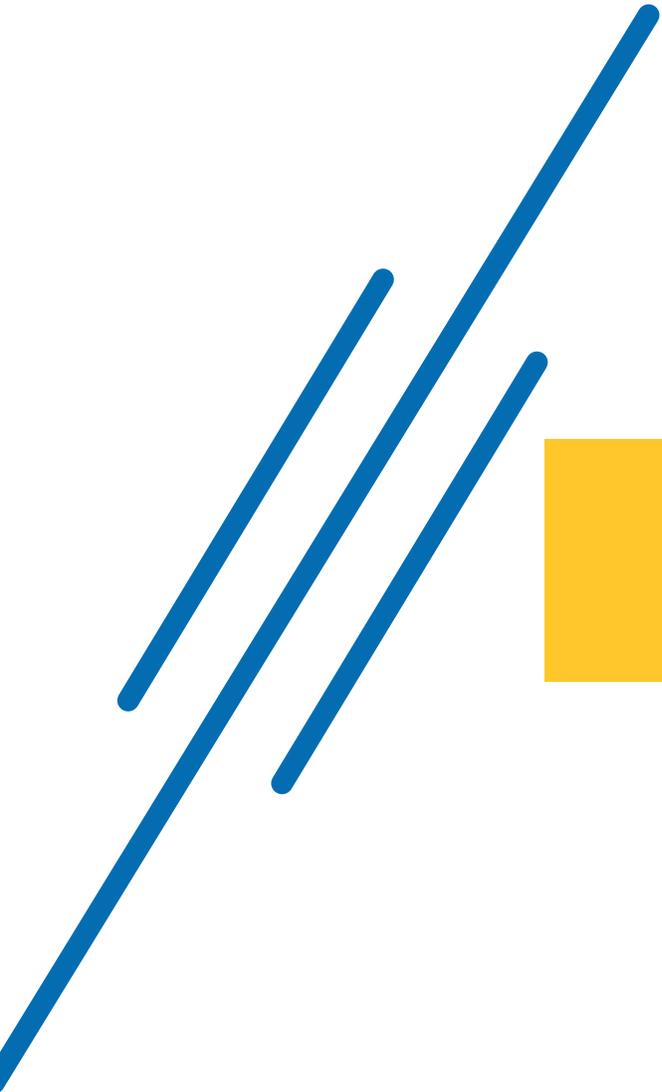
Draft USCDI v5
General Recommendations

Draft USCDI v5 General Recommendations

The IS WG supports ONC's addition of all proposed data elements and data classes included in Draft USCDI v5.

Based on the review and discussion, the IS WG makes the following detailed recommendations on definitions and scope of specific data elements and classes.

Draft USCDI v5 Recommendations

IS-WG-2024_ Recommendation – 01

- **Regarding the two Clinical Notes data elements Emergency Department Note and Operative Note, the WG recommends that ONC choose a "at minimum" LOINC code different than the LOINC code used respectively for the full structured documents.**
  - The designated codes could be chosen as part of the subsequent data modeling discussions

IS-WG-2024_ Recommendation – 02

- **Recommend that ONC change the name of the *Test Kit Unique Device Identifier* data element to *Test Kit Identifier* in USCDI v5.**

  - The name change emphasizes that the test kit identifier data element uniquely identifies the reagent name and manufacturer (similar to the make and model of a car) that was used to obtain the Test Result Value.

  - It should be specified that this data element is required to be sent if present/available and that inclusion in USCDI does not imply a requirement of collection.

  - The device identifier should be based on the FDA Unique Device Identification System when available, or other appropriate schema when not available.

IS-WG-2024_ Recommendation – 03

- **Recommend that ONC create a new *Advance Healthcare Directive* (AHD) data class.**

  - Recommended definition: Documentation of presence and properties of patient expressed goals, preferences and priorities should a patient be unable to communicate them to a provider. Examples of AHD include Advance Directives, Durable Medical Power of Attorney, Living Will, and Personal Advance Care Plan.

  - The Draft USCDI v5 data element Advance Directive Observation should be removed from the Observation data class.

  - This new data class should also include the following data elements: AHD Documentation Observation, AHD Unstructured Documents/Plan, and AHD Structured Documents/Plan.

  - WG recommend referencing the Treatment Intervention Preference and Care Experience Preference data elements in both the Goals/Preferences and the new AHD data class.

IS-WG-2024_ Recommendation – 04

- **Recommend that ONC revise the definition for the data element *Sex Parameter for Clinical Use*.**

  - Recommended definition: A use-specific sex-related categorization value that provides guidance on how a recipient should apply settings or reference ranges and interpret results of the associated test, image, or procedure.

  - Recommended usage note: SPCU value(s) should be based upon information such as an anatomical inventory, hormone lab tests, genetic testing, menstrual status, obstetric history, etc.

  - Note that there are more recent available LOINC versions than the version referenced in the HTI-1 Final Rule for Sex Parameter for Clinical Use. The IS WG notes these more recent LOINC versions reflect an updated minimum value set for Sex Parameter for Clinical Use.

IS-WG-2024_ Recommendation – 05

- **The HITAC supports ONC's adding the *Orders* data element, adding:**
    - Recommended usage notes: Inclusion of this data element does not imply full workflow management support from order to performance, result, and back to ordering provider, only review of available order details at point of query and/or document generation. Orders should contain relevant details regarding ordering provider, CCed provider(s), and patient that would be necessary to carry out the order and route any results appropriately.
    - The long term goal for the Orders data class should be to include all existing, not yet completed/cancelled, orders signed by a provider - including active (e.g., current inpatient orders), outstanding (i.e., ordered but not yet performed), standing/recurrent, future (i.e., to be performed at a specified time in the future) - including the details provided at the time of order that would be necessary for any order to be carried out (e.g., order date/time, ordering provider, order code, indication(s), associated diagnoses, priority, expected date/time of completion, order number, order expiration date).

IS-WG-2024_ Recommendation – 06

- **The HITAC supports ONC's adding the *Author* and *Author Role* data elements, adding:**
  - In response to ONC's public query as to sufficient implementation of these data elements to warrant inclusion of the data element in USCDI v5. The ISWG's members believe that there is sufficient implementation.
  - Additionally, there are some nuances about which word is used to capture the generic "author" concept, and the USCDI data element definition addresses these nuances. For example, "author" and "performer" are used, with their respective definitions in respective FHIR IGs, but they all seem to fit within and demonstrate use of the general "author" data element as defined by ONC in draft v5 ("actor that participated in creation or revision of the data"), combined with the "author role" data element ("category of actor that participated in the creation or revision of data", e.g., "provider, patient, family member, and device"). For example, the US Core Implementation Guide STU6, FHIR v.4.0.1, uses "author" (person who answered question about the subject) in the QuestionnaireResponse Profile and "performer" (person responsible for the observation) in the Simple Observation Profile. Practitioners, organizations, patients, devices, care teams, etc., are listed as examples. The Structured Data Capture FHIR IG STU3, FHIR v4.0.1, uses "Performer" similarly in the Questionnaire performer type. The SDOH Clinical Care for Multiple Domains IG STU2.1, FHIR v4.0.1, SDOHCC Observation Screening Response does the same for observations.

IS-WG-2024_ Recommendation – 07

- **Recommend ONC clarify which data elements and classes are relevant to the *Encounter Location* data element.**
  - FHIR US Core/C-CDA is enumerating a reasonable set that USCDI should reflect directly.

Level 2 Data Elements Not Included in Draft USCDI v5

IS-WG-2024_ Recommendation – 08

- **Recommend that ONC add the data element *Care Plan* to the *Patient Summary and Plan* data class:**
  - Recommended definition: Shared dynamic longitudinal plan representing all Care Team Members (including patient/caregiver) prioritized concerns, goals, interventions, and evaluation/outcomes across all health and care settings.

  - Recommended examples include the Multiple Chronic Condition eCare Plan, the electronic Long-Term Services & Supports (LTSS) Plan, and the CDA® Release 2 Consolidated CDA Template for Care Plan.

  - Recommended Usage note: Include care team members, assessments, problems, identified goals for the patient/person and provider, procedures/interventions, and outcomes/evaluations.

    Continued…

IS-WG-2024_ Recommendation – 08 (continued)

- **Recommend that ONC add the data element *Care Plan* to the *Patient Summary and Plan* data class:**
  - Usage note: The Care Plan data element will often integrate or link to specific values or codes from other data elements essential to care planning, especially in the following data classes:
  - Care Team Members
  - Health Status
  - Goals and Preferences
  - Procedures
  - Outcomes / Evaluation
    - To be developed but can sometimes be represented as the comparison of two Assessments.
  - Members of a care team may often think of these collectively as a Care Plan class, even though the data classes and elements are used for a variety of use cases.

IS-WG-2024_ Recommendation – 09

- **Recommend that ONC rename the *Patient Summary and Plan* data class as *Care Plan* data class.**

  - The "Assessment and Plan of Treatment" data element would remain a narrative.

  - If the other recommendations are adopted, the "Care Plan" data class would include the elevated "Care Plan" data element and the "Assessment and Plan of Treatment" data element.

IS-WG-2024_ Recommendation – 10

- **Recommend that ONC develop an *Outcomes/Evaluations* data element or class.**

IS-WG-2024_ Recommendation – 11

- **Recommend that ONC includes health literacy as an additional example domain in the Social Determinants of Health (SDOH) data element definitions.**
    - ONC should highlight specific SDOH domains of interest, without requiring all HIT adopt all such example domains, rather consider those relevant to the HIT's context and user community.
    - A full and constantly evolving list of relevant SDOH domains should be maintained in the ISA.
    - These elements are contained within Gravity Project SDOH elements as an addressed social risk domain. ISWG supports the work of ONC and Gravity to have Interoperability Standards Advisory pages for all Gravity domains, and regular updates to the USCDI SDOH element descriptions with new domains in the aim of assisting implementers.

IS-WG-2024_ Recommendation – 12

- **Recommend that ONC add the data element Specimen Collection Date/Time in the Laboratory data class to USCDI v5.**
  - It is an essential data element to understand lab result validity and to equity in using results for treatment.
  - This data element is required by CLIA (493.1276(a)).

IS-WG-2024_ Recommendation – 13

- **Recommend that ONC add *Substance (Food)* as a data element in the *Allergies and Intolerances* data class to USCDI v5.**
  - Recommended definition: "Common food substances and allergens that can cause harmful or undesirable physiological responses when exposed to the substance or the substance is consumed."
  - Applicable standard: SNOMED CT®

IS-WG-2024_ Recommendation – 14

- **Recommend that ONC add *Criticality* as a data element in the *Allergies and Intolerances* data class to USCDI v5.**
  - Recommended the definition included in the submitted Level 2 data element: "Estimate of the potential clinical harm, or seriousness, of a reaction to an identified substance."

IS-WG-2024_ Recommendation – 15

- **Recommend that ONC add Family Health History as a data element in a new Family Health History data class in USCDI v5.**

  - Definition: A patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in §170.207(a)(12).

  - Usage note: At a minimum, the data element enables a user to record, change, and access information about a patient's first degree relative within the said patient's record.

  - Standards: SNOMED CT is the baseline standard to capture this data element, although health IT developers are allowed to use other standards, such as LOINC, to capture elements of family health history.

IS-WG-2024_ Recommendation – 16

- **Recommend that ONC add *Portable Medical Order* (PMO) as a data element in the *Orders* class in USCDI v5.**

  - The WG supports the current definition of PMO in Level 2: "Orders for certain aspects of medical care, including end-of-life care, which support a transfer of care request from one practitioner or organization to another that provides end-of-life or life-sustaining care services. Different types of portable medical orders are used in different jurisdictions."

IS-WG-2024_ Recommendation – 17

- **Recommend that ONC add the *Maternal Social Determinants of Health Note* data element to the *Clinical Notes* data class in USCDI v5.**
  - This aligns with ONC's priority to advance health data needs for providing equitable care to underserved communities while addressing a national crisis.
  - Inclusion of this data element supports the White House's Blueprint for Addressing the Maternal Health Crisis by ensuring intentional capture of essential data to support maternal and child health.
  - The Maternal Social Determinants of Health Note does what existing clinical notes do not and collects the most critical information maternal care providers need to capture and share regarding the status of a maternal patient's social determinants of health.
  - This note would enable all to collect and exchange the data needed to advance maternal health care and outcomes for women in all communities.
  - The US maternal mortality rate is the highest of any developed nation with African American and Alaskan Native/Indigenous American women more likely to die from pregnancy related causes.

IS-WG-2024_ Recommendation – 18

- **Recommend that ONC explore the presentation of data elements in USCDI specific to maternal health considering the high priority of addressing maternal mortality.**
  - This could be in the form of a new data class (e.g., Maternal and Newborn Health) and/or another way to identify or display the data elements in USCDI that are essential for maternal and newborn health care.

IS-WG-2024_ Recommendation – 19

- **Recommend that ONC adds the following Level 2 data elements in the *Health Insurance Information* data class:**
  - Coverage Period
  - Medicare Patient Identifier
  - Payer Name
  - Plan Name
  - Group Name
  - Usage note: This data class is associated with the overall primary and secondary coverage for the individual. In some cases, it may be different from the benefit used for a particular encounter or claim (e.g., worker's comp benefits).

IS-WG-2024_ Recommendation – 20

- **Recommend that ONC advances specific medication administration event data elements to enable access to individual administration data used in various analytics and research contexts.**
  - Currently, data on medication administration events is only partially addressed with the existing data elements Fill Status and Medication Adherence. These data give some insight into the status of the medication administration(s) resulting from a medication order or prescription and a patient's self-administration of these medications.
  - However, more specific data are needed where medications are administered in an institutional setting. These are of particular interest to other parties outside of the institutions for purposes such as research.
  - For example, the proposed Level 2 Medication Administration Status, Medication Administration Route, and the existing element Procedure Performance Time (which reflects medication administration time) more completely address medication administration event specific data elements in an upcoming USCDI version.

IS-WG-2024_ Recommendation – 21

- **Recommend that ONC add *Facility Address* data element to complement other data elements in the *Facility Information* data class such as *Facility Name*, *Facility Identifier*, and *Facility Type*.**
  - This would provide the necessary information to identify specific physical institution or facility to link service and outcome data.

IS-WG-2024_ Recommendation – 22

- **Recommend that ONC add *Device Used* data element to the *Medical Devices* data class.**
  - o Applicable vocabulary standard: LOINC
  - o This data element would allow for the capture of commonly used categories of devices, including:
    - 95131-9 (Mobility [wheelchair])
    - 95025-3 (Manual Wheelchair.Most Dependent)
    - 95022-0 (Does the person use a motorized wheelchair and/or scooter)
    - 95027-9 (Motorized Wheelchair/Scooter.Usual)
    - 95042-8 (in the past month, has the person used, or expressed or demonstrated a need for an assistive device?)
    - 94887-7 (Limb prosthesis)
    - 94890-1 (Reacher/Grabber)
    - 94892-7 (Orthotics/Brace)
    - 94901-6 (Communication device)
    - The element list should be expanded in consultation with appropriate stakeholder groups including health care providers, payers, and patient groups, especially those representing individuals with disabilities

IS-WG-2024_ Recommendation – 23

- **Reiterate the ISWG recommendation from April 2023 for ONC to change the name and definition of *Sex* to become an example of a *Recorded Sex or Gender*, e.g., recorded at birth.**
  - This would allow the capture and exchange of more nuanced information, which is essential for proper care and can support patient care, care coordination, and quality measurement. This is a critical data element because, depending on context, the value may change and not be the static value on an original birth certificate.

IS-WG-2024_ Recommendation – 24

- **Reiterate the ISWG recommendation from April 2023 for ONC to expand the definition of the *Gender Identity* data element to include the Gender Harmony Project's minimum value set in addition to the current USCDI Standards.**
  - Gender Harmony Project minimum value set includes:
    - Female
    - Male
    - Nonbinary
    - Unknown

IS-WG-2024_ Recommendation – 25

- **Recommend that ONC add *Vaccination Event Record Type* data element to the *Immunizations* data class.**
    - This data element distinguishes whether a vaccination is based on the historical record or was administered at the facility submitting the vaccine.
    - It can already be exchanged via HL7 v2.5.1 and 2.8.2 Implementation Guides.

IS-WG-2024_ Recommendation – 26

- **Recommend that ONC add *Health Care Agent* data element to the *Advance Healthcare Directive* data class.**
  - Designating a healthcare agent is a valuable part of advance care planning that should be captured in an Advance Directives data class, if available.

Recommendations for Future Consideration

IS-WG-2024_ Recommendation – 27

- **Recommend that ONC advance the *Signature* data element in the *Provenance* data class to Level 1.**
  - Vocabulary and functional standards are not sufficiently advanced to merit inclusion in USCDI v5, but merit elevation to Level 1 to advance further discussion and consideration in the future.
  - Signature is required as part of the MDS, IRF-PAI, LCDS, and HIS assessments.
  - They leverage LOINC codes supporting this data element, including:
    - 85814-2 (IRF-PAI Signature of persons completing the assessment) 85647-6 (Signature of person collecting or coordinating collection of assessment information Provider)
    - 85648-4 (Signature of persons completing the assessment)
    - 70127-6 (Signature verifying assessment completion)

IS-WG-2024_ Recommendation – 28

- **Recommend that ONC continue to evaluate methods to synchronize and align USCDI with FHIR US Core and C-CDA to provide clarity and assist with implementation.**

IS-WG-2024_ Recommendation – 29

- **Recommend that ONC continue to evaluate whether USCDI criteria should be broadly applied to all paths to certification given the limited scope and use cases of certain EHRs and other health IT that might benefit from certification.**

Discussion

HITAC Vote