ONC | HealthIT ADVISORY COMMITTEE

Interoperability Standards Workgroup

RECOMMENDATIONS ON DRAFT USCDI VERSION 5

Report to the Health Information Technology Advisory Committee

April 11, 2024

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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Background

On January 18, 2024, ONC published its Draft United States Core Data for Interoperability Version 5 (USCDI v5) and the companion Health IT Standards Bulletin 2024-1, and sought public feedback on the data classes and elements included in this version and data elements not included in this version. As part of this public feedback process, ONC also charged the Health Information Technology Advisory Committee (HITAC) and the Interoperability Standards Workgroup (IS WG) to make specific recommendations on the final content in the USCDI v5.

ONC CHARGE TO THE INTEROPERABILITY STANDARDS WORKGROUP (IS WG)

Overarching Charge

The IS WG was charged with evaluating Draft USCDI v5 and providing recommendations to the HITAC by April 11, 2024, to inform the final version of USCDI v5 which ONC expects to publish in July 2024.

Detailed Charge

The workgroup's specific charge was to:

Evaluate Draft USCDI v5 and provide HITAC with recommendations for:

1a - New data classes and elements included in Draft USCDI v5 published in January 2024

1b - Level 2 data classes and elements not included in Draft USCDI v5

ADDITIONAL BACKGROUND INFORMATION

The IS WG membership consists of an engaged group of subject matter experts representing various stakeholder groups, including direct patient care, patient advocacy, health IT development, standards development organizations, and others. The Appendix to this document reflects the workgroup's membership at the time these recommendations were finalized.

Within the scope of the above charges, the workgroup addressed several specific questions on which ONC requested input during the public feedback period of January 18 to April 15, 2024, including:

1. Suggestions for improvement in the data classes or elements in Draft USCDI v5, including:
    a. Data class and data element definitions
    b. Examples of code sets used by health IT developers and implementers to communicate data element scope.
2. Should other data elements, classified as Level 2 on the USCDI web pages, be added to USCDI v5 instead, or in addition to those in Draft USCDI v5? If so, why?
3. Are there significant barriers to development, implementation, or use for any of these data elements that warrant a change in definition, or removal from Draft USCDI v5?

In addition to the general discussions, the workgroup invited several outside subject matter experts to give testimony regarding their areas of expertise, interest, and work. These presenters also took questions from workgroup members to inform their decisions. These included:

- On February 20, 2024, Carol Macumber (Clinical Architecture) and Rob McClure, (MD Partners) spoke on behalf of the Gender Harmony Project and the data elements they submitted for addition to USCDI, including *Sex Parameter for Clinical Use*, *Pronoun*, and *Name to Use*, all of which were included in Draft USCDI v5.
- On February 27, 2024, Maria Moen (MyDirectives) presented her outlook and recommendations on two data elements included in Draft USCDI v5, *Advance Directive Observation* and *Orders*. There was a robust discussion on these and other related data elements being considered for USCDI v5.
- And finally, on March 5, 2024, the workgroup heard from Jenna Norton (National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases), Arlene Bierman (Agency for Healthcare Quality and Research), Liz Palena-Hall (Centers for Medicare and Medicaid Services), and Evelyn Gallego (EMI Advisors) who discussed the value and definition of the data element *Care Plan*, a Level 2 data element. They provided their recommendations for the definition and scope of this data element and the data class in which they feel it belongs.

Recommendations

INTRODUCTION

The focus of the IS WG work was to make specific recommendations on new data classes and elements included in Draft USCDI v5 and those previously submitted data elements that were mature enough to be designated Level 2 by ONC but not included in Draft USCDI v5.

WORKGROUP RECOMMENDATIONS

New Data Classes and Elements in Draft USCDI v5

The IS WG supports the addition of all 13 proposed data elements and two data classes included in Draft USCDI v5. The WG also makes the following detailed recommendations on definitions and scope of specific data elements and classes. Data elements with consensus approval without comment are not detailed below.

- **IS-WG-2024_ Recommendation – 01 – Regarding the two Clinical Notes data elements *Emergency Department Note* and *Operative Note*, the WG recommends that ONC choose an "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.
  - As a step towards a full unique device identifier, inclusion of this data element is an essential first step in being able to support comparability of test results for clinical care, public health reporting, importing results from and quality monitoring of patient point of care home devices, and use of Real-World Evidence for regulatory decision making and addressing health inequity in underserved communities. ONC should continue efforts to identify and mitigate infrastructure gaps that limit the capture and transmission of the production identifier components of the test kit unique device identifier (UDI) in currently non-certified heath Information technology, such as LIS.
  - 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* 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 recommends referencing the Treatment Intervention Preference and Care Experience Preference data elements in both the Goals/Preferences and the new AHD data class.
  - Rationale/Usage Note: Referencing a data element in multiple data classes where it is relevant to be related to for context, such as these preferences or facility information for different data classes, enhances clarity and reduces ambiguity on the intended scope of USCDI. Subsequent inclusion in supporting interoperability standards can specifically address how the references are managed.

- **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 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).
  - Initial prioritization should include medication (including OTC and PRN), laboratory, and imaging orders as these are well standardized and ordering capabilities are required for health IT certification.
  - Advance Directive orders, e.g., Do Not Resuscitate (DNR) and Physician's Order for Life Sustaining Therapies (POLST), are unique orders that should eventually be portable and actionable. These orders may be supported by jurisdictional requirements, e.g., specific forms completed. In the absence of industry standards for the contents of advance directive orders, the recipient should at a minimum be able to see that an order has been placed, by whom, and when so that they could potentially reach out to the source to gather relevant details and/or documentation.
  - Plan to address nursing, therapies, dietary, admit/discharge/transfer orders, portable medical orders, etc., in subsequent USCDI versions.

  - Orders need not be placed exclusively in a unique data class. Each order type should also be included in the applicable class.
  - Many orders require specific data for the test, service, or item requested. As such, the Orders data class should focus on the data elements common to most orders, while orderable-specific data requirements should be addressed in data elements in the applicable domain-specific data class. For example, order data specific to diagnostic imaging test orders should be included in the Diagnostic Imaging class, laboratory tests in the Laboratory class, interventions, referrals and consultations in the Procedures class, etc. Within each relevant data class, an Order data element should specify the details that are required for the specific order type, e.g., Laterality would apply to imaging orders, while Dose and Route would apply to medication orders.

- **IS-WG-2024_ Recommendation – 06 – The HITAC supports ONC 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 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.
  - 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:
    - Care Team Members data class & elements: Care Team Name, Care Team Identifier, Care Team Role, Care Team Location, Care Team Telecom
    - Health Status Assessments data class & elements: Health Concerns, Functional Status, Disability Status, Mental/Cognitive Status, Pregnancy Status, Alcohol Use, Substance Use, Physical Activity, SDOH Assessment, Smoking Status
    - Problems data class & elements: Problems, SDOH Problems/Health Concerns, Date of Diagnosis, Date of Resolution
    - Goals and Preferences data class & elements: Patient Goals, SDOH Goals, Treatment Intervention Preference, Care Experience Preference
    - Procedures / Interventions data class & elements: Procedures, Performance Time, SDOH Interventions, Reason for Referral
    - Outcomes / Evaluation data class or element: 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 health IT adopt all such example domains, rather consider those relevant to the health IT context and user community.
  - A full and constantly evolving list of relevant SDOH domains should be maintained in the Interoperability Standards Advisory (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 ISA 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 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.
  - Inclusion of this data element supports the White House's Blueprint for Addressing the Maternal Health Crisis by facilitating exchange 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).
  - Align the naming of Medicare Patient Identifier with CMS's use of Medicare Beneficiary Identifier.
  - While these data elements are already included in the latest FHIR US Core and C-CDA implementation guides referenced in HTI-1, the implementation community can benefit from more clarity on how to consistently populate these fields--in particular Payer Name and Group Name--as there is variation between what a typical insurance card shows vs. what is best used on real-time eligibility (RTE) queries with health plans.

- **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.
  - Specifically identifying these in a dedicated Medication Administration data class would furthermore remove any ambiguity whether current USCDI versions intend and imply that data about the individual medication administration events is already addressed or not.
  - This recommendation and approach should be considered in context of Recommendation 05, adding an Orders data class and data elements that identifies a need to recognize general order data applicable to any order, as well as having order data specific to a domain such as Procedures, Laboratory, Medications, Immunizations, Images, etc., identified as well.
  - This happens with events documenting the Procedures, Medications Administration, Immunizations, Laboratory Test Report, etc. as well where some event data is common, while other is very specific to the domain it occurs.
  - We ask ONC to consider improved methods of representing concepts more clearly to ensure there is no ambiguity as to what data is applicable and in scope of USCDI from and ordering vs. scheduling vs. performing (administration, result reporting, procedure, etc.) perspective.

- **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.**
    - Applicable vocabulary standard: LOINC
    - 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.**

Appendix

WORKGROUP ROSTER

NAME	Organization
Sarah DeSilvey* (Co-Chair)	Gravity Project
Steven Eichner* (Co-Chair)	Texas Department of State Health Services
Pooja Babbrah	Point-of-Care Partners
Shila Blend*	North Dakota Health Information Network
Ricky Bloomfield	Apple
Medell Briggs-Malonson*	UCLA Health
Hans Buitendijk*	Oracle Health
Keith Campbell**	Food and Drug Administration
Christina Caraballo	HIMSS
Grace Cordovano	Enlightening Results
Raj Dash	College of American Pathologists
Derek De Young*	Epic
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Hannah Galvin*	Cambridge Health Alliance
Rajesh Godavarthi*	MCG Health, part of the Hearst Health Network
Jim Jirjis**	Centers for Disease Control and Prevention
Steven Lane	Health Gorilla
Hung Luu*	Children's Health
Anna Mccollister*	Individual
Katrina Miller Parrish*	Humana Health Insurance
Alex Mugge**	Centers for Medicare & Medicaid Services

Aaron Neinstein*	Notable
Kikelomo Oshunkentan*	Pegasystems
Rochelle Prosser*	Orchid Healthcare Solutions
Mark Savage	Savage & Savage LLC
Fillipe Southerland*	Yardi Systems, Inc.
Shelly Spiro	Pharmacy Health Information Technology Collaborative
Zeynep Sumer-King*	NewYork-Presbyterian
Naresh Sundar Rajan*	CyncHealth

* HITAC Member ** HITAC Federal Representative