Health Information Technology Advisory Committee℠

The Office of the National Coordinator for Health Information Technology

Interoperability Standards Workgroup Report to the Health Information Technology Advisory Committee

PHASE 1 - RECOMMENDATIONS ON DRAFT USCDI VERSION 3

April 13, 2022

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Background

Leveraging significant input from the Health Information Technology Advisory Committee (HITAC) and its United States Core Data for Interoperability (USCDI) Task Force, ONC published USCDI version 2 in July 2021, the first annual update to a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The USCDI Task Force provided recommendations on the expansion process ONC established to update USCDI, including additional criteria ONC could use to prioritize and select among submitted data elements for inclusion in future versions of USCDI. These additional criteria focused on data classes and elements that could address health equity disparities, respond to the needs of underserved communities, and advance public health data interoperability. ONC applied these new criteria to its evaluation of over 200 public submissions for new data elements and a similar number of comments and feedback on previously submitted data elements received through the ONC New Data Element and Class (ONDEC) Submission System during the USCDI v3 submission cycle.

On January 13, 2022, ONC published its Draft USCDI Version 3 and the companion Health IT Standards Bulletin 2022-1, and sought public feedback on the data classes and elements included in this version, as well as on data elements that ONC did not include, and requested additional feedback on a number of specific data elements. As part of this public feedback process, ONC charged the HITAC with establishing a new workgroup, the Interoperability Standards Workgroup (IS WG) to make specific recommendations on the final content in the USCDI v3.

ONC CHARGES TO THE INTEROPERABILITY STANDARDS WORKGROUP

Overarching Charge

The IS WG was charged with evaluating Draft USCDI v3 and providing recommendations by April 13, 2022, regarding the final version of USCDI v3 which is expected to be published in July 2022.

ONC also charged the IS WG with identifying opportunities to update the ONC Interoperability Standards Advisory (ISA) to address HITAC priority uses of health IT, including related standards and implementation specifications. This second charge will be addressed by making recommendations to the HITAC by June 16, 2022.

Detailed Charge

The workgroup's first specific charge was to:

Evaluate Draft USCDI v3 and provide HITAC with recommendations for:

> 1a - New data classes and elements included in Draft USCDI v3 published in January 2022
> 1b - Level 2 data classes and elements not included in Draft USCDI v3

ADDITIONAL BACKGROUND INFORMATION

The IS WG includes 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 roster included in Appendix A 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 13 to April 30, 2022. These questions included:

1. Are there any improvements needed in the data classes or elements included in Draft USCDI v3, including:
    a. Appropriate and meaningful data class and element names and definitions?
    b. Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?
2. Should other data elements classified as Level 2 be added to USCDI v3 instead, or in addition to those included in Draft USCDI v3? If so, why?
3. Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?

The workgroup also developed recommendations responsive to ONC's request for feedback on several data elements that were already included in the final USCDI v2, including Sex (Assigned at Birth), Gender Identity, and Current and Previous Address. To assist in the development of these recommendations, the workgroup invited several outside subject matter experts to give testimony regarding their areas of expertise, interest, and work. These included:

Carol Macumber, MS, Clinical Architecture, and Rob McClure, MD, MD Partners, presented on February 8, 2022 and discussed the Gender Harmony Project and its approach to addressing several sex and gender related data elements which have been the focus of the project's work. This testimony directly informed the workgroup's recommendations on the data elements Sex (Assigned at Birth) and Gender Identity.

ONC's IT Specialist Carmen Smiley, the co-lead of Project US@, presented information on the project's work to develop and publish the first Unified Specification for Address in Health Care on February 15, 2022 to inform the workgroup's recommendations on the Current Address and Previous Address data elements in Draft USCDI v3.

On March 1, 2022, the workgroup heard several presentations by experts on the topics of disability and functional status assessment which informed the work group's recommendations on the new Health Status data class in Draft USCDI v3. These presentations were by:

1. Closing Disability Disparities
    a. Megan A. Morris, PhD, MPH, CCC-SLP, University of Colorado Anschutz Medical Campus
    b. Bonnielin K. Swenor, PhD, MPH, Johns Hopkins University Disability Health Research Center

        c.   Silvia Yee, MA, LL.B, Disability Rights Education and Defense Fund (DREDF)

2. Disability and Functional Status Assessment terminology
   a. Holly Miller, MD, MBA, FHIMSS
   b. Terry O'Malley, MD
3. International Classification of Functioning, Disability and Health (ICF)
   a. Matt Elrod, PT, DPT, MEd

Recommendations

INTRODUCTION

The focus of the IS WG's Phase 1 work was to make specific recommendations on new data classes and elements included in Draft USCDI v3, data elements that were mature enough and feasible to be designated "Level 2" by ONC but not included in Draft USCDI v3, and barriers to development, implementation, and/or use of any data elements that would warrant not including them in USCDI v3.

TASK FORCE RECOMMENDATIONS

New Data Classes and Elements in Draft USCDI v3

The ISWG supports the new data elements and data classes included in Draft USCDI v3 and makes the following detailed recommendations on specific proposed data elements and classes. The WG acknowledges that some data elements included in Draft USCDI v3 and the additional data elements recommended below may require additional development in the applicable exchange implementation specifications, such as HL7® FHIR® US Core and C-CDA Companion guides. The WG understands that there may be implementation barriers identified by HL7 that could impact the inclusion in USCDI v3 of one or more recommended data elements.

- **IS-WG-2022-Phase 1_ Recommendation 01 – Recommend that ONC rename the Health Status data class as Health Status/Assessments and specify LOINC as the applicable vocabulary standard.**

    - In making this recommendation, we clarify that the intent is *not* for every EHR to be able to collect/produce every possible health assessment, but rather to make any assessments that are produced available for interoperability, and to accept any assessment received via exchange at least as textual output indexed according to the accompanying LOINC code.

- **IS-WG-2022-Phase 1_ Recommendation 02 – Recommend that ONC leave the Health Concerns data element in the current (USCDI v2) Health Concerns data class as opposed to moving into the new Health Status data class**

- **IS-WG-2022-Phase 1_ Recommendation 03 – Recommend that ONC establish a robust set of terms representing Health Status/Assessment data elements Functional Status, Disability Status, and Mental/Cognitive Status**

    - These data elements should represent, at a minimum, structured, standardized assessments with associated LOINC codes. As noted in our recommendation on Assessments, these may include self-assessments provided by the individual.

- Appendix B contains seven recommended questions for Disability Status, self-reported by the individual, and suggested example terms and codes for Functional Status and Mental/Cognitive Status.

- The data element labeled "Mental Function" in Draft USCDI v3 should be labeled "Mental/Cognitive Status".

- ONC should work with stakeholders over time to identify additional value sets of standardized assessments with accompanying LOINC codes for these data elements, including value sets representing learning disability, mental disability, autism/social disability, and caregivers' disability status.

- **IS-WG-2022-Phase 1_ Recommendation 04 – Recommend that ONC consider referencing the International Classification of Functioning, Disability, and Health (ICF) model as a value set applicable to the Health Status/Assessments data class.**

  - ICF uses an established hierarchy of concepts in 4 categories (possibly applicable as data elements):

    - Body Function

    - Body Structure

    - Activities and Participation

    - Environmental Factors

  - The ICF enables standardized, reproducible, and interoperable capture and exchange of functioning and disability information for individuals.
  - The ICF is supported by the payer and clinical communities with multiple standard assessment tools (e.g., CMS: IRF-PAI, Patient-Reported Outcomes Measurement Information System (PROMIS), AM-PAC, etc.)

- **IS-WG-2022-Phase 1_ Recommendation 05 – Recommend that ONC specify that the data elements in the Health Status/Assessments data class may be populated with patient generated health data by either or both:**

  - Accommodating self-assessments with appropriate LOINC codes, or
  - Adding the Author data element to the Provenance data class to indicate that the source of assessment data is the individual.

- **IS-WG-2022-Phase 1_ Recommendation 06 – Recommend that ONC clarify that the intent of the Related Person and Related Person's Relationship data elements within the Patient Demographics data class is to identify relationships for medical record linkage, patient matching, and similar demographic purposes and to distinguish this from the roles of care team members.**

- **IS-WG-2022-Phase 1_ Recommendation 07 – Recommend that, for the Pregnancy Status data element within the Health Status data class, in addition to pregnant, not pregnant, and unknown, ONC add a value capturing intent to become pregnant.**

    - This additional value of "pregnancy intent" is to inform care such as medication prescribing, as medications can affect fertility as well as safety in early pregnancy

    - Work with stakeholders to draft and add other value set items to document important pregnancy-related statuses such as preconception, prenatal period, pregnancy loss, postpartum period, and interpregnancy period.

- **IS-WG-2022-Phase 1_ Recommendation 08 –Recommend that ONC provide clarification of the intent for the Reason for Referral data element within the Procedures data class with appropriate examples.**

    - Recommend clarity regarding whether the collection of this data element would be required by all certified HIT. This clarification is needed across all of USCDI.

- **IS-WG-2022-Phase 1_ Recommendation 09 – Recommend that ONC change the name of the Reason for Referral data element within the Procedures data class to Reason/Indication for Referral or Procedure.**

    - This alternative name would better describe the appropriate purpose and scope of the data element

- **IS-WG-2022-Phase 1_ Recommendation 10 – Recommend that USCDI v3 specifies SNOMED-CT as an applicable vocabulary standard for the Specimen Type data element in the Laboratory data class.**

    - ONC should also consider specifying the following value sets defined by HL7®

        - HL7VS-specimenType

        - FHIR v2 Specimen Type

- **IS-WG-2022-Phase 1_ Recommendation 11 – Recommend that ONC specify the applicable vocabulary standard for the Values/Results data element within the Laboratory data class as SNOMED CT for qualitative lab result, and UCUM for numerical results.**

- **IS-WG-2022-Phase 1_ Recommendation 12 – The initial scope of the Health Insurance Information data class and its component data elements should be the overall primary and secondary coverage for the individual.**

    - In some cases, the health insurance information and benefit for a particular encounter or claim may be different from the individual's overall insurance coverage (e.g., in the case of worker's comp encounters).

    - We recommend that ONC work with stakeholders, including X12, NCPDP and HL7 to align the minimum initial vocabulary and value set for Coverage Type and to extend this over time.

Level 2 Data Elements Not Included in Draft USCDI v3

- **IS-WG-2022-Phase 1_ Recommendation 13 – Recommend that ONC add the data element Author to the Provenance data class in USCDI v3.**

    ○ This data element is especially relevant in conjunction with patient-generated health data (PGHD) and patient-reported outcomes (PROs).
    ○ If ONC thinks that Author should not be included across the board, we recommend at the very least that ONC include Author in USCDI v3 for the following data elements that typically represent self-reported data and thus warrant identifying the individual as the author when applicable:
        ■ Race/Ethnicity
        ■ Gender Identity
        ■ Sexual Orientation
        ■ Disability Status
        ■ Pregnancy Status

- **IS-WG-2022-Phase 1_ Recommendation 14 – Recommend the following Level 2 data elements be added to USCDI v3:**
        ■ Family Health History
        ■ Problems: Date of Onset
        ■ Allergies: Substance (non-medication)
        ■ Allergies: Substance (food)
        ■ Travel Information

    ○ The scope and definition for these data elements should include both clinical observations and patient reported data (PGHD).

- **IS-WG-2022-Phase 1_ Recommendation 15 – Recommend ONC add support for Averaged values of multiple observations of the Systolic and Diastolic Blood Pressure data elements within the Vital Signs data class as recommended by the AMA and AHA M.A.P. program.**

    ○ Recommend that ONC work with stakeholders to determine how to best accommodate this utilizing LOINC codes or other means.

- **IS-WG-2022-Phase 1_ Recommendation 16 – Recommend that USCDI V3 include Facility Level Identifier, using an Organizational Identifier with combination of Identifier and Assigning Authority.**

- - Recommend that the defined set of Assigning Authorities include national organization identifiers in common use, which would need to accommodate NPI, CCN and PTAN
  - Recommend that multiple identifiers be included or allowed. We recommend that USCDI v3 identify the Organization Identifier with the encounter. This data should be required if known.

Data Elements in Prior Versions of USCDI

- **IS-WG-2022-Phase 1_ Recommendation 17 – Recommend ONC clarify that the Discharge Summary data element within the Clinical Notes data class refers to the unstructured narrative clinical note portion of a Discharge Summary and does not imply the specification of or requirement for discrete data elements.**

- **IS-WG-2022-Phase 1_ Recommendation 18 – Recommend that USCDI V3 include all note types coded in the LOINC Document Ontology.**

  - Should ONC not adopt this recommendation, we recommend, at a minimum, the addition of the Surgical Operation Note (LOINC 11504-8) and Tumor Board Notes (LOINC 85231-9) to the current list of Clinical Note types included in USCDI.
  - ONC should clarify the Clinical Notes data elements include narrative or free text data and do not require CDA® formatted structured documents.
  - For purposes of clarity, this recommendation is not intended to suggest that all certified health IT need to generate all possible note types, but that when notes are documented/captured, they should be indexed with the appropriate associated LOINC code, and that when notes are received, they are received with the context provided by the associated LOINC code to support queries based on note type.
  - For purposes of conformance testing, ONC should consider working with stakeholders on creation of a core value set of note types to be tested.
  - ONC should consider encouraging LOINC to develop a new code to designate legacy notes not coded more specifically at the time of their creation or subsequently.

- **IS-WG-2022-Phase 1_ Recommendation 19 – Recommend that ONC clarify that the Smoking Status data element within the Health Status data class may be represented using any of several specific assessment instruments and include a set of examples.**

- **IS-WG-2022-Phase 1_ Recommendation 20 – Recommend that ONC include in USCDI v3 a fully scoped Medication data class that includes all the data elements that are included in current Health IT Certification criteria, using NCPDP SCRIPT, FHIR and C-CDA, including:**
    - Dose
    - Strength
    - Formulation
    - Sig/Dosing Instructions
    - Route
    - Status

- **IS-WG-2022-Phase 1_ Recommendation 21 – Recommend that ONC adopt the Project US@ specification as the applicable vocabulary standard for Current Address and Previous Address in the Patient Demographics data class. This recommendation includes:**

    - Current and Previous Address should contain not only the components of address (number, street name, city, state, zip) in accordance with the Project US@ specification, but also must contain a value or values from the Patient Address Metadata Schema, which is able to represent homelessness or temporary addresses.
    - ONC should consider encouraging and supporting the use of an additional metadata element indicating the content model used (i.e., Non-normalized / pre-Project US@ vs. Project US@ compliant, including the applicable AHIMA Companion Guide).

- **IS-WG-2022-Phase 1_ Recommendation 22 – Recommend that ONC include in USCDI v3 the Gender Harmony Project's five data elements (Gender Identity, Sex for Clinical Use, Recorded Sex or Gender, Name to Use, and Pronouns) and their specified minimum value sets.**

    - These data elements work together collectively to represent sex and gender diversity in support of improved care and outcomes for gender-marginalized people.
    - Regarding Gender Identity, recommend that alignment should include the GHP's minimum value set while keeping two fields from USCDI that add critical data:
        - GHP: Gender Identity:
            1. Female
            2. Male
            3. Nonbinary
            4. Unknown
        - USCDI: Gender Identity:
            1. Additional gender category or other, please specify

2. Choose not to disclose
- ○ Recommend changing label and definition of Sex Assigned at Birth to become one part of Recorded Sex or Gender, i.e., recorded at birth.
- ○ Recommend that Gender Identity remain in the Patient Demographics data class, and that Name to Use and Pronouns be included in that class as well.
  - ■ Gender Identity, Name to Use, and Pronouns should be specified as typically being self-reported by the individual.

- ○ Recorded Sex or Gender may be clinical values derived through clinical assessment or legal documentary sources.
- ○ Sex for Clinical Use should be specified as context dependent and should not be interpreted as a singular assessment. For some patient populations, Sex for Clinical Use may be different at the same point in time for different assessments or procedures (e.g., imaging studies vs. laboratory assessments).
- ○ Therefore, consistent with other data elements and recommendations, recommend including associated metadata identifying the source (e.g., individual self-report, clinical observation) and method of collecting values for each data element.

- **IS-WG-2022-Phase 1_ Recommendation 23 – Recommend that ONC include in USCDI v3 the following additional Level 2 Laboratory data elements that are already included in CLIA and mapped to existing certification requirements for FHIR, C-CDA and ELR specifications.**
  - ■ Unit of Measure
  - ■ Laboratory results: Date and time stamps
  - ■ Laboratory Test Performed Date
  - ■ Specimen Source Site
  - ■ Test Kit Unique Identifier

- ○ It should be specified that these data elements are required to be sent if present/available and that their inclusion in USCDI does not imply a requirement of collection.

WG Recommendations for Future ONC Focus

A. The WG requests that ONC charge the workgroup with further exploration and development of recommendations regarding the data elements that would be valuable in a future version of USCDI to support the interoperability of important lists of medications including Current Medication List and Discharge Medications.
- In this effort it would be useful to point USCDI at the content models implied by IGs used in Health IT certification in addition to vocabulary standards and to assess the need for additions to these content models.
- While ONC has removed the certification requirements to maintain these lists, it is important to represent these lists when clinically maintained for interoperability.

B. The WG requests that ONC charge the workgroup with further exploration of and development of recommendations regarding the data models necessary to support the interoperability of discrete laboratory test results and include additional applicable data elements in the future.

C. The WG encourages ONC to explore how to support the exchange of qualifiers regarding collection and measurement of vital signs (e.g. supine vs. seated BP) in future versions of USCDI and point to existing LOINC support for such qualifiers.

D. The WG encourages ONC to work with stakeholders to develop a new data element, Accommodations, within the appropriate data class to support care for a person with disabilities.

E. The WG encourages ONC to work with stakeholders to advance the Laboratory Reference Range and Interpretation (Level 1) data elements, which are required by CLIA and already referenced by existing Health IT certification criteria so that they can be included in a future version of USCDI.

Appendix A

TASK FORCE ROSTER

Name	Organization
Steven Lane (Co-Chair)	Sutter Health
Arien Malec (Co-Chair)	Change Healthcare
Kelly Aldrich	Vanderbilt University
Hans Buitendijk	Cerner
Thomas Cantilina	DOD
Christina Caraballo	HIMSS
Grace Cordovano	Enlightening Results
Steven Eichner	Texas Dept. of State Health Services
Adi Gundlapalli	CDC
Rajesh Godavarthi	MCG Health
Jim Jirjis	HCA Healthcare
Kensaku Kawamoto	University of Utah Health
Leslie Lenert	Medical University of South Carolina
Hung S. Luu	Children's Health
David McCallie	Individual
Clem McDonald	National Library of Medicine
Mark Savage	Savage & Savage LLC
Michelle Schreiber	CMS
Abby Sears	OCHIN
Ram Sriram	NIST

Appendix B

RECOMMENDED TERMS FOR HEALTH STATUS DATA ELEMENTS

- Disability Status data element value set should include the following questions from American Community Survey (U.S. Census) and the international Washington Group on Disability Statistics:
    1. Are you deaf or do you have serious difficulty hearing?
    2. Are you blind or do you have difficulty seeing, even when wearing glasses?
    3. Do you have serious difficulty walking or climbing stairs?
    4. Do you have difficulty concentrating, remembering, or making decisions?
    5. Do you have difficulty dressing or bathing?
    6. Do you have difficulty doing errands alone such as visiting a doctor's office or shopping?
    7. Using your usual language, do you have difficulty communicating (for example, understanding or being understood)?
- Mental/Cognitive Status
    1. Mini Mental Evaluation - LOINC 72107-6
    2. Mini-Addenbrooke's Cognitive Examination (MACE) – SNOMED CT 273249006
    3. Neuropsychological batteries – SNOMED CT (e.g., LURIA 273581001)
    4. Glasgow Coma Scale – LOINC 35088-4
    5. Mini-Mental State Examination [MMSE] - LOINC 72107-6
    6. MOCA – LOINC 72133-2
    7. SLUMS – LOINC 71492-6
    8. PHQ 2 – LOINC 55757-9
    9. PHQ 9 – LOINC 44249-1
    10. GAD-7 – LOINC 69737-5
    11. Alcohol Use Disorder Identification Test (AUDIT-C) - LOINC 72109-2
    12. Drug Abuse Screen Test-10 (DAST-10) - LOINC 82666-9
    13. Tobacco, alcohol, prescription medications, and other substance use assessment (TAPS) - LOINC 96845-3
    14. Geriatric Depression Scale (GDS) panel – LOINC 48542-5
    15. Humiliation, Afraid, Rape, and Kick questionnaire (HARK) - LOINC 76499-3
- Functional Status
    1. ADLs/IADLs – LOINC 57048-1
    2. Barthel index – LOINC 96762-0
    3. Fall Risk (Morse Fall Scale) – LOINC 59460-6
    4. Pressure Ulcer risk level (Braden scale) – LOINC 81636-3
    5. Self-care activities- functional ability panel – LOINC 83180-0

6. Timed Up and Go Test – LOINC 89422-0
7. Functional assessment of Incontinence Therapy-Fecal – LOINC 70831-3
8. Functional Assessment of Incontinence Therapy-Urinary – LOINC 70837-0
9. Norton scale – LOINC 75248-5
10. Karnofsky Performance Scale – LOINC 89243-0
11. Functional Assessment of Chronic Illness Therapy (FACIT) – LOINC 70504-6
12. Visual Analog Scale – LOINC 38214-3
13. Brief Pain Inventory – LOINC 77564
14. Functional Capacity Evaluation LOINC 47420-5