Interoperability Standards Workgroup Recommendations on Draft USCDI Version 4 Report to the HITAC

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April 12, 2023

Agenda

- IS WG Roster
- IS WG Charge
- IS WG Workplan
- IS WG Draft USCDI v4 Recommendations
- Level 2 Data Elements Not Included in Draft USCDI v4 Recommendations

Interoperability Standards Workgroup Roster

Name	Organization	Name	Organization
Sarah DeSilvey* (Co-Chair)	Gravity Project Larner College of Medicine at the University of Vermont	**Naresh Sundar Rajan* (Co-Chair)**	CyncHealth
Pooja Babbrah	Point-of-Care Partners	Hung Luu*	Children's Health
Shila Blend*	North Dakota Health Information Network	Margaret Marshall**	Department of Veterans Affairs
Ricky Bloomfield	Apple	Anna McCollister*	Individual
Hans Buitendijk*	Oracle Health	Clem McDonald*	National Library of Medicine
Christina Caraballo	HIMSS	Deven McGraw*	Invitae Corporation
Grace Cordovano	Enlightening Results	Aaron Miri*	Baptist Health
Raj Dash	College of American Pathologists	Aaron Neinstein*	UCSF Health
Steven Eichner*	Texas Department of State Health Services	Kikelomo Oshunkentan*	Pegasystems
Nedra Garrett**	Centers for Disease Control and Prevention	Mark Savage	Savage & Savage LLC
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Michelle Schreiber**	Centers for Medicare and Medicaid Services
Bryant Thomas Karras*	Washington State Department of Health	Shelly Spiro	Pharmacy HIT Collaborative
Steven Lane*	Health Gorilla	Ram Sriram**	National Institute of Standards and Technology

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Interoperability Standards Workgroup Charge

Overarching charge: Review and provide recommendations on the Draft USCDI Version 4

Specific charge:

	Due
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	April 12, 2023

Key Workgroup Meetings and Areas of Focus

IS WG Meeting	Areas of Focus
• February 15, 2023	New Draft USCDI v4 data elements
• February 22, 2023	New Draft USCDI v4 data elements (Medications & Laboratory)
• March 1, 2023	Physical Activity, Medication Instructions/Adherence
• March 8, 2023	Treatment Intervention/Care Experience Preferences
• March 15, 2023	Facility Information
• March 22, 2023	Diagnostic Imaging data elements*

*Data elements not included in Draft USCDI v4

Charge (a) – New Data Classes and Elements from Draft USCDI v4

Rationale:

- Address straightforward elements early to develop familiarity with the process
- Identify elements of community concern, such as advanced care planning, and schedule them with enough time to notify public and ensure representation

Allergies and Intolerances
- Substance (Non-Medication)

Encounter Information
- Encounter Identifier

Health Status Assessments
- Alcohol Use
- Substance Use
- Physical Activity

Facility Information
- Facility Identifier
- Facility Type
- Facility Name

Vital Signs
- Average Blood Pressure

Laboratory
- Result Unit of Measure
- Result Reference Range
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition and Disposition

Procedures
- Time of Procedure

Medications
- Medication Instructions
- Medication Adherence

Goals (related to the advance care planning process)
- Treatment Intervention Preference
- Care Experience Preference

SME Presentations

March 1, 2023	Physical Activity	Laurie Whitsel and Paul Chase, AHA, Lloyd McKenzie, Dogwood Health
	Medication Instructions/Adherence	Scott Robertson, KP
March 8, 2023	Treatment Intervention Preference	Holly Miller, MedAllies, Maria Moen, ADVault
	Care Experience Preference	Terry O'Malley Maria Moen, ADVault
March 15, 2023	Facility Information	Michelle Schreiber, CMS Abigail Viall, CDC
March 22, 2023	Diagnostic Imaging elements	Brian Bialecki, ACR Dr Keith Dreyer, ACR Mike Tilkin, ACR

Draft USCDI v4 Recommendations

IS WG Recommendations Report Format

Background

Charge (a) Draft USCDI v4 data element recommendations

Charge (b) Level 2 data element recommendations

Recommendations for Future Consideration

IS-WG-2023_ Recommendation – 01

- **Recommend that ONC add Allergies and Intolerances - Substance (Non-Medication) with clarification that this extends the existing elements to cover non-medication substances.**

IS-WG-2023_ Recommendation – 02

- **Recommend that ONC add Health Status Assessments - Alcohol Use and reference the specific LOINC codes mentioned in the submission. The WG further recommends adding SNOMED CT as an applicable vocabulary standard.**

IS-WG-2023_ Recommendation – 03

- **Recommend that ONC add Health Status Assessments - Substance Use and reference the specific LOINC codes mentioned in the submission.**

IS-WG-2023_ Recommendation – 04

- **Recommend that ONC work with CDC, CMS, state, tribal, local, and territorial agencies and other key healthcare and public health authorities to identify and evolve appropriate vocabulary standards for Facility Information - Facility Type.**
  - Standards for Facility Type should be defined to maintain clear differentiation from encounter location and associated standards.

IS-WG-2023_ Recommendation – 05

- **Recommend that ONC include the following applicable standards for Facility Information - Facility Identifier:**
  - CMS Certification Number (CCN)
  - Provider Transaction Access Number (PTAN)
  - National Provider Identifier (NPI)
  - Clinical Laboratory Improvement Amendments identification numbers (CLIA)

IS-WG-2023_ Recommendation – 06

- **Recommend that ONC specify that Vital Signs - Average Blood Pressure includes, at minimum, the following LOINC codes as applicable vocabulary standards:**

  - 96607-7 Blood pressure panel mean systolic and mean diastolic
  - 96608-5 Systolic blood pressure mean
  - 96609-3 Diastolic blood pressure mean

IS-WG-2023_ Recommendation – 07

- **Recommend that ONC reference the following code system as an applicable standard for Laboratory – Result Interpretation:**
  - https://terminology.hl7.org/CodeSystem-v3-ObservationInterpretation.html, as it has been harmonized across HL7 v2, CDA, and FHIR.
  - We note further that Result Interpretation is required by CLIA* (493.1291) and suggest adding this citation to the definition to emphasize its importance.

*CLIA = Clinical Laboratory Improvement Amendments

IS-WG-2023_ Recommendation – 08

- **Recommend that ONC add language to the definitions of the following data elements that they are required by CLIA (493.1291).**
  - Reference Range
  - Result Unit of Measure
  - Specimen Source Site

IS-WG-2023_ Recommendation – 09

- **Recommend that ONC specify in its definition of Laboratory - Specimen Identifier that it is intended to include the accession number assigned to the specimen.**
  - This data element is required by CLIA (493.1276(a))

IS-WG-2023_ Recommendation – 10

- **Recommend that ONC rename the proposed Laboratory - Specimen Condition and Disposition data element to Specimen Exception Annotation.**

  - Specimen Exception Annotation:
    - Information regarding the condition and disposition of specimens not meeting the laboratory's criteria for acceptability relevant to the performance or non-performance of a test as required by CLIA (493.1291).

IS-WG-2023_ Recommendation – 11

- **Recommend that ONC does not use Procedures – Time of Procedure to represent the collection date/time for a laboratory test.**

IS-WG-2023_ Recommendation – 12

- **Recommend that ONC make the following changes to the Medications – Medication Instructions data element:**
  - Include specific components included in structured and codified SIG (patient directions)
    - Route of administration
    - Quantity
    - Timing of hours
    - Special instructions

IS-WG-2023_ Recommendation – 13

- **Recommend that ONC make the following changes to the Medications - Medication Adherence data element:**
  - Include two specific components
    - Adherence codes (e.g., taking, not taking as directed, stopped, discontinued)
    - Reason for patient non-adherence.
    - Examples of reasons for non-adherence include: (1) Indication e.g., duplicate therapy (2) Effectiveness e.g., medication not effective (3) Safety e.g., adverse effect (4) Adherence e.g., cost too much, etc.

IS-WG-2023_ Recommendation – 14

- **Recommend that ONC rename the Goals data class to Goals and Preferences.**
  - This change will better accommodate the range of concepts therein including Patient Goals, SDOH Goals, and the new data elements Treatment Intervention Preference and Care Experience Preference.

IS-WG-2023_ Recommendation – 15

- **Recommend that ONC add Health Status Assessments - Physical Activity and reference the specific LOINC codes of the base measures mentioned in the submission.**

Level 2 Data Elements Not Included in Draft USCDI v4 Recommendations

IS-WG-2023_ Recommendation – 16

- **Recommend that ONC rename the Patient Summary and Plan Data Class to Patient Care Plan, and the Assessment and Plan of Treatment data element to Care Plan Summary.**
  - ONC should work with interested parties to quickly develop these core structured data elements beyond a narrative summary into a Care Plan data class in order to help meet immediate needs. This makes a critical advance, moving Care Plan to a more shareable data class.

IS-WG-2023_ Recommendation – 17

- Recommend that ONC include Advance Directive in USCDI v4, with an immediate priority focused on establishing an on-ramp for access to currently available unstructured advance directive documents (e.g., PDFs and scanned images), and

- Include Advance Directive as a care plan type in the Care Plan data class, as per Recommendation 16, to enable access to structured data from advance directives.

IS-WG-2023_ Recommendation – 18

- **Recommend that ONC add the following Clinical Notes to USCDI v4:**
  - Operative Note
    - LOINC 11504-8 as the generic or minimum note code
  - Emergency Department Notes
    - LOINC 15507-7 Emergency Department Progress Note and LOINC 59258-4 Emergency Department Discharge Summary as the “generic” or minimum note codes.

IS-WG-2023_ Recommendation – 19

- **Recommend that ONC add the following data elements, definitions, and value sets from the Gender Harmony Project to USCDI v4:**
  - Gender Identity
    - Female
    - Male
    - Nonbinary
    - Unknown
    - USCDI defined values:
      - Additional gender category or other, please specify
      - Choose not to disclose
  - Sex for Clinical Use
  - Recorded Sex or Gender
  - Name to Use
  - Pronouns

IS-WG-2023_ Recommendation – 20

- **Recommend that ONC change the name and definition of Sex to become an example of a Recorded Sex or Gender, e.g., recorded at birth.**

IS-WG-2023_ Recommendation – 21

- **Recommend that Gender Identity remain in the Patient Demographics/Information data class. When added, Name to Use and Pronouns should be in the Patient Demographics/Information Data Class. Gender Identity, Name to Use, and Pronouns should be self-reported by the individual.**

IS-WG-2023_ Recommendation – 22

- **Recommend that ONC add metadata capturing source for the data elements Sex for Clinical Use and Recorded Sex or Gender (e.g., individual self-report, clinical observation) and method of collecting values for each data element.**

IS-WG-2023_ Recommendation – 23

- **Recommend that ONC change the name of the Laboratory - Test Performed Date/Time data element to Specimen Collection Date/Time (Clinically Relevant Observation Time) and add Specimen Collection Date/Time (Clinically Relevant Observation Time) as a data element in USCDI v4.**
  - This data element represents the most clinically relevant time point in which to interpret the result. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field represents the date and time the specimen was obtained from a patient and collected into a container or obtained.
  - This alternative name would better describe the appropriate purpose and scope of the data element.
  - This data element should accommodate time zone differences.
  - The above data elements should be combined.

IS-WG-2023_ Recommendation – 24

- **Recommend that ONC change the name of the Lab Test Report Date/Time data element to Laboratory Result Report Date/Time and add Laboratory Result Report Date/Time as a data element in USCDI v4.**
  - Represents the most recent timestamp associated with completion of all components.

IS-WG-2023_ Recommendation – 25

- **Recommend that ONC add Laboratory - Test Kit device name and manufacturer name to USCDI v4.**
  - ONC should initially include the device name and manufacturer component of the test kit/device(s) and address the barriers to including the full UDI in the next USCDI version.

IS-WG-2023_ Recommendation – 26

- **Recommend that ONC add Provenance - Author in USCDI v4.**
  - Relevant for *patient-generated health data* (PGHD) and patient-reported outcomes (PROs).
  - We recommend ONC include Author in USCDI v4 for the following USCDI and draft USCDI v4 data elements that emphasize self-reported data
    - Race
    - Ethnicity
    - Gender Identity
    - Sexual Orientation
    - Disability Status
    - Pregnancy Status
  - and the following Level 2 data elements that capture important PGHD and, further, advancing these Level 2 data elements to USCDI v4:
    - Family Health History
    - Problems: Date of Onset
    - Allergies: Substance (non-medication) [e.g., latex]
    - Allergies: Substance (food)
    - Travel Information [e.g., COVID-19, Zika]

IS-WG-2023_ Recommendation – 27

- **Recommend data elements that may be used to capture patient-generated health data (PGHD) and to support its bidirectional exchange in USCDI v4:**
  - Family Health History
  - Reported Medication
  - Problems: Date of Onset
  - Pregnancy Status (intent to become pregnant)
  - Nutrition & Diet
  - Substance Use (draft v4)
  - Allergies: Substance (non-medication) (draft v4)
  - Allergies: Substance (food)
  - Social History
  - Travel Information

IS-WG-2023_ Recommendation – 28

- **Recommend including the following three Diagnostic Imaging data elements in USCDI V4:**
  - Imaging Reference
  - Requested Procedure Identifier
  - Accession Number

While not all Health IT systems currently capture, maintain, or share information to access and view DICOM images, the requirement to *exchange it when available* would significantly advance the ability for individuals and providers to access and use diagnostic images and data files utilizing broadly available technology and would support current implementations of DICOM image file access and use within or outside networks such as Carequality and the Trusted Exchange Framework (TEFCA).

IS-WG-2023_ Recommendation – 29

- **Recommend that ONC add Facility Information - Facility Address to USCDI v4.**
  - Facility address is part of a core set of facility-level data elements needed to link data to a specific physical place of service or resource.

IS-WG-2023_ Recommendation – 30

- **Recommend that ONC add Medications - Medication Prescribed Code and Medication Route to USCDI v4 as they are important data elements for quality measurement and public health.**
  - Medication Prescribed Code
    - Change the element definition to “A code (or set of codes) that specify medication prescribed or ordered, and to include textual description if no code is available." In addition the applicable code sets would be RxNorm and NDC.
  - Medication Route
  - ONC should work with stakeholders to define elements for documenting data elements for medication administration statuses.

IS-WG-2023_ Recommendation – 31

- **Recommend that ONC adds Vaccinations - Vaccination Event Record Type data element to USCDI v4.**

IS-WG-2023_ Recommendation – 32

- **Recommend that ONC adds Orders - Orders for End of Life Care data element to USCDI v4.**

IS-WG-2023_ Recommendation – 33

- **Recommend that ONC expand the definitions of the following Health Status Assessments data elements to include not only the specified assessment questions but also the responses or results of the assessments:**
  - Functional Status
  - Disability Status
  - Mental/Cognitive Status

  These changes would align with the PACIO Project IGs.

  Assessment data collected by health professionals, as well as patient generated health data collected from surveys or questionnaires, may be used for multiple purposes: including quality reporting, prior authorization, payments, utilization review, survey and certification, and more.

Recommendations for Future Consideration

IS-WG-2023_ Recommendation – 34

- **Recommend that ONC re-evaluate Organization – Organization Identifier as a Level 2 data element for consideration for addition to future versions of USCDI.**
  - Update the definition and/or the applicable standards to include NHSN Org ID as one of the applicable, widely used national standards.
  - ONC should collaborate with CMS to evaluate moving the CCN from the currently proposed Facility Information data class to the Organization data class.

Discussion

HITAC Vote