Overview of United States Core Data for Interoperability (USCDI) Version 4

Al Taylor, MD
Medical Informatics Officer
Office of Technology

August 17, 2023

Agenda

- USCDI v4 Overview

- ONDEC Changes

- USCDI v5 Submission Cycle

- Review of HITAC Recommendations to ONC

USCDI Version 4
July 2023

New Data Elements in USCDI v4

Allergies and Intolerances
- Substance (Non-Medication) ✚

Encounter Information
- Encounter Identifier ✚ 🔍

New Data Class

Facility Information
- Facility Identifier ✚ 🔍
- Facility Type ✚ 🔍
- Facility Name ✚ 🔍

Goals and Preferences
- Treatment Intervention Preference ⚌ ⬆
- Care Experience Preference ⚌ ⬆

Health Status Assessments
- Alcohol Use § 🧠
- Substance Use ✚ 🧠
- Physical Activity § ⬆

Laboratory
- Result Unit of Measure ✚ 🔍
- Result Reference Range ✚ 🔍
- Result Interpretation ✚ 🔍
- Specimen Source Site ✚ 🔍
- Specimen Identifier ✚ 🔍
- Specimen Condition Acceptability ✚ 🔍

Medications
- Medication Instructions ✚
- Medication Adherence ✚

Procedures
- Performance Time 🔍

Vital Signs
- Average Blood Pressure ✚

⚌ Equity Based ⬆ Underserved 🔍 Public Health 🧠 Behavioral Health ✚ Add'l USCDI Needs § ONC Cert

USCDI United States Core Data for Interoperability

USCDI Version 4

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Identifier
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Facility Information
- Facility Identifier
- Facility Type
- Facility Name

Goals and Preferences
- Patient Goals
- SDOH Goals
- Treatment Intervention Preference
- Care Experience Preference

Health Insurance Information
- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Identifier
- Payer Identifier

Health Status Assessment
- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability

Medical Devices
- Unique Device Identifier - Implantable

Medications
- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

Patient Demographics/ Information
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan
- Assessment and Plan of Treatment

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- Performance Time
- SDOH Interventions
- Reason for Referral

Provenance
- Author Time Stamp
- Author Organization

Vital Signs
- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)

USCDI: Transparent, Predictable, Collaborative

USCDI Version Highlights

- USCDI v1 is required by Cures Act Final Rule and added data classes clinical notes and provenance, and data elements pediatric vital signs and address

- USCDI v2 added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH).

- USCDI v3 added 24 data elements focused on factors promoting equity, reducing disparities and supporting public health data interoperability.

    - Proposed as new required version in Health Data, Technology, and Interoperability 1, with an effective date of December 31, 2024

- USCDI v4 added Alcohol and Substance Use Assessments, Physical Activity, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements.

Prioritization Criteria for New USCDI Data Elements

- Healthcare disparities and inequities

- Underserved communities

- Behavioral health

- Public health

- Key additions over past USCDI versions

- Modest burden for

  - Standards and implementation guide developers

  - Health IT developers

  - Providers and health systems implementing updates

- Aggregate lift for all new data elements

ONDEC Changes

ONDEC Changes – USCDI v5 and Beyond

USCDI ONDEC (ONC New Data Element and Class) Submission System

The deadline for new submissions for USCDI v5 is September 20, 2023, at 11:59 p.m. EDT. Submissions after this date will be considered for USCDI v6.

How It Works

Search ONDEC for the same or similar data elements. You can connect with other submitters and collaborate to strengthen a submission by commenting on them rather than submitting a duplicate entry.

Search within USCDI [🔍]

Step 1. Submit new data elements and classes

Review Prep Sheet   See questions and prepare content for your submission - updated to include more information on ONC's evaluation of submissions

Start My Submission   Registered ISA users only - login or create account here

Step 2. ONC evaluates and assigns a level to each data element depending on the overall value, maturity and challenges to implementation

• Level 0 • Level 1 • Level 2   **View Leveling Criteria**

Step 3. ONC posts submitted data elements on the USCDI page by level

Submitters will have an opportunity to add or change information which could change its level determination.

Other stakeholders can review these submissions and contribute to their development through comments and collaboration with original submitters.

Step 4. Deadline for new submissions for USCDI v5 is September 20, 2023 at 11:59 ET.

Step 5. ONC anticipates publishing Draft USCDI v5 in January 2024.

ONDEC Changes – Level Criteria Language

USCDI Data Element Leveling Criteria

ONC evaluates all submissions and assigns a level based on four criteria.

Return to ONDEC

- Level 2 data elements are most mature and are considered for future versions of USCDI.
- Level 1 and Level 0 determinations are used to identify areas of additional work needed to meet the criteria for a higher level and consideration for future versions of USCDI.
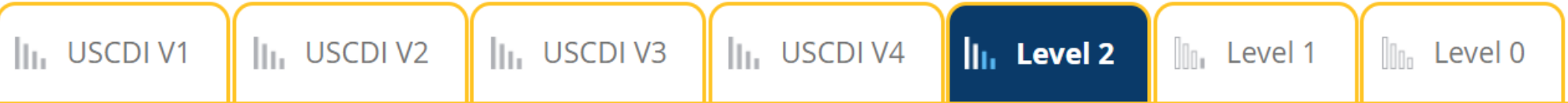
Submitters can provide updates with additional information to justify a higher level and consideration.

	Criterion #1 Maturity - Current Standards	Criterion #2 Maturity - Current Use	Criterion #3 Maturity - Current Exchange	Criterion #4 Use Case(s) - Breadth of Applicability
LEVEL 2	Data element is represented by a terminology standard or SDO-balloted technical specification or implementation guide.*	Data element is captured, stored, or accessed in multiple production EHRs or other HIT modules from more than one developer.	Data element is electronically exchanged between more than two production EHRs or other HIT modules of different developers using available interoperability standards.	Use cases apply to most care settings or specialties.
LEVEL 1	Data element is represented by a terminology standard or SDO-balloted technical specification or implementation guide.*	Data element is captured, stored, or accessed in at least one production EHR or HIT module.	Data element is electronically exchanged between two production EHRs or other HIT modules using available interoperability standards.	Use cases apply to several care settings or specialties.
LEVEL 0	Data element is not represented by a terminology standard or SDO-balloted technical specification or implementation guide.	Data element is captured, stored, or accessed in limited settings such as a pilot or proof of concept demonstration.	Data element is electronically exchanged in limited environments, such as connectathons or pilots.	Use cases apply to a limited number of care settings or specialties, or data element represents a specialization of other, more general data elements.

*Maturity-Standard criterion is the same for Level 1 and Level 2. Data elements meeting this level of maturity will be assigned Level 2 for this criterion.

Level Criteria Language – Level 2

USCDI V1	USCDI V2	USCDI V3	USCDI V4	**Level 2**	Level 1	Level 0

Level 2 data elements meet the following criteria:

- **Represented by a terminology standard or SDO-balloted technical specification or implementation guide.**
- **Data element is captured, stored, or accessed in multiple production EHRs or other HIT modules from more than one developer.**
- **Data element is electronically exchanged between more than two production EHRs or other HIT modules of different developers using available interoperability standards.**
- **Use cases apply to most care settings or specialties.**

Level Criteria Language – Level 1

| III. USCDI V1 | III. USCDI V2 | III. USCDI V3 | III. USCDI V4 | III. Level 2 | **III. Level 1** | III. Level 0 |

Level 1 data elements meet the following criteria:

- **Represented by a terminology standard or SDO-balloted technical specification or implementation guide.**
- **Data element is captured, stored, or accessed in at least one production EHR or HIT module.**
- **Data element is electronically exchanged between two production EHRs or other HIT modules using available interoperability standards.**
- **Use cases apply to several care settings or specialties.**

Level Criteria Language – Level 0 (Previously Comment)

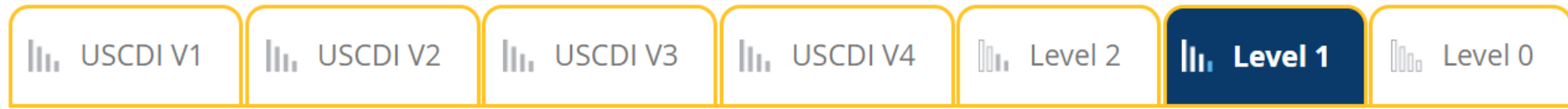| USCDI V1	USCDI V2	USCDI V3	USCDI V4	Level 2	Level 1	**Level 0**
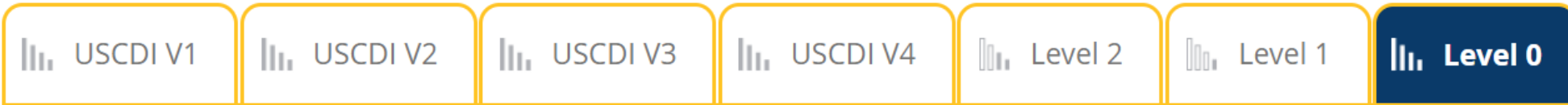
Level 0 data elements meet the following criteria:

- **Not represented by a terminology standard or SDO-balloted technical specification or implementation guide.**
- **Captured, stored, or accessed in limited settings such as a pilot or proof of concept demonstration.**
- **Data element is electronically exchanged in limited environments, such as connectathons or pilots.**
- **Use cases apply to a limited number of care settings or specialties, or data element represents a specialization of other, more general data elements.**

USCDI v5 Submission Timeline

USCDI Timeline

- July 20, 2023
  - USCDI v4, Standards Bulletin published
  - USCDI v5 submission cycle opened

- September 20, 2023
  - USCDI v5 submission cycle ends

- January 2024 (Tentative)
  - Draft USCDI v5 release

2023 HITAC/IS WG Recommendations

IS WG Recommendations Report, April 12, 2023:
https://www.healthit.gov/sites/default/files/page/2023-05/2023-04-12_IS_WG_USCDI_v4_Transmittal_Letter_508.pdf

IS WG Recommendations Report Format

Part 1 - Draft USCDI v4 data element recommendations

Part 2 - Level 2 data element recommendations

Part 3 - Recommendations for Future Consideration

Draft USCDI v4 Data Element Recommendations

IS WG Recommendations – Part 1

HITAC recommended adoption of all the data elements in Draft USCDI v4, and made the additional recommendations for specific USCDI v4 data elements:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
01	Allergies and Intolerances	Substance (Non-Medication)	Expansion of existing data elements	Adopted
02	Health Status Assessments	Alcohol Use	Reference specific LOINC codes	Examples added
03	Health Status Assessments	Substance Use	Reference specific LOINC codes	Examples added
15	Health Status Assessments	Physical Activity	Reference specific LOINC codes	Examples added
04	Facility Information	Facility Type	Develop appropriate vocabulary	Future work
05	Facility Information	Facility Identifier	Specify applicable standard	Future work

IS WG Recommendations – Part 1

Rec #	Data Class	Data Element	Recommendation	ONC Activity
06	Vital Signs	Average Blood Pressure	Reference specific LOINC codes	Examples added
07	Laboratory	Result Interpretation	HL7 ObservationInterpretation Code System	Adopted (Optional)
08	Laboratory	Reference Range	State that these data elements are required by CLIA (493.1291)	Not adopted
08	Laboratory	Result Unit of Measure		Not adopted
08	Laboratory	Specimen Source Site		Not adopted
09	Laboratory	Specimen Identifier	State inclusion of accession number	Adopted (example)
10	Laboratory	Specimen Condition and Disposition	Rename Specimen Exception Annotation	Specimen Condition Acceptability

IS WG Recommendations – Part 1

Rec #	Data Class	Data Element	Recommendation	ONC Activity
11	Procedures	Time of Procedure	Do not represent date/time for laboratory test	Not included in examples
12	Medications	Medication Instructions	Change definition, require components	Adopted – definition change and components referenced in usage notes
13	Medications	Medication Adherence	Change definition, require "reason for non-adherence"	Partially adopted, future submission
14	Goals		Change name to Goals and Preferences	Adopted

Level 2 Data Element Recommendations

IS WG Recommendations – Part 2

HITAC made recommendations on existing data elements and classes, or those in Level 2 but not added to USCDI:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
16	Patient Summary and Plan	Assessment and Plan of Treatment	Rename both class and name	Not adopted – Care Plan still candidate
17	Care Plan	Advance Directive	Add data element	Not adopted – Still candidate
18	Clinical Notes	Operative Note	Add data element	Not adopted – Still candidate
18	Clinical Notes	Emergency Department Progress Note	Add data element	Not adopted – Still candidate
19	Patient Demographics/ Information	Sex for Clinical Use, Recorded Sex or Gender, Name to Use, Pronouns	Add data elements	Not adopted – Still candidate

IS WG Recommendations – Part 2

HITAC made recommendations on existing data elements and classes, or those in Level 2 but not added to USCDI:

	Data Class	Data Element	Recommendation	ONC Activity
19	Patient Demographics/ Information	Sex for Clinical Use, Recorded Sex or Gender, Name to Use, Pronouns	Add data elements	Not adopted – Still candidate
20	Patient Demographics/ Information	Sex	Change to example of Recorded Sex or Gender	Not adopted – Still candidate
22	Patient Demographics/ Information	Sex for Clinical Use	Add Metadata – Source and Method	Not adopted – Still candidate
22	Patient Demographics/ Information	Recorded Sex or Gender	Add Metadata – Source and Method	Not adopted – Still candidate

IS WG Recommendations – Part 2

HITAC made recommendations on existing data elements and classes, or those in Level 2 but not added to USCDI:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
23	Laboratory	Test Performed Date/Time	Change name/add	Not adopted – Still candidate
24	Laboratory	Lab Test Report Date/Time	Change name/add	Not adopted – Still candidate
25	Laboratory	Test Kit Device Name/Manufacturer	Add data element	Not adopted – Still candidate
26	Provenance	Author	Add data element	Not adopted – Still candidate
27	Multiple	Multiple	Add data elements, allow for PGHD source	Source not specified – PGHD allowed

IS WG Recommendations – Part 2

HITAC made recommendations on existing data elements and classes, or those in Level 2 but not added to USCDI:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
28	Diagnostic Imaging	Imaging Reference	Add data element	Not adopted – More development needed
28	Diagnostic Imaging	Requested Procedure Identifier	Add data element	Not adopted – More development needed
28	Diagnostic Imaging	Accession Number	Add data element	Not adopted – More development needed
29	Facility Information	Facility Address	Add data element	Not adopted – Still candidate
30	Medications	Prescribed Code, Route	Add data elements	Not adopted – Still candidates

United States Core Data for Interoperability

IS WG Recommendations – Part 2

HITAC made recommendations on existing data elements and classes, or those in Level 2 but not added to USCDI:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
31	Immunizations	Vaccination Event Record Type	Add data element	Not adopted – Still candidate
32	Orders	Orders for End-of-Life Care	Add data element	Not adopted – Still candidate
33	Health Status Assessments	Functional Status	Include responses in data elements	Not adopted – Still candidate
33	Health Status Assessments	Disability Status	Include responses in data elements	Not adopted – Still candidate
33	Health Status Assessments	Mental/ Cognitive Status	Include responses in data elements	Not adopted – Still candidate

Recommendations for Future Consideration

United States Core Data for Interoperability

IS WG Recommendations – Part 3

HITAC made recommendations on data elements not in USCDI or Level 2:

Rec #	Data Class	Data Element	Recommendation	ONC Activity
34	Organization	Organization Identifier	Advance to Level 2	Not adopted – Still candidate

Thank you!

Al Taylor, MD

Albert.Taylor@HHS.gov

HealthIT.gov