ONC

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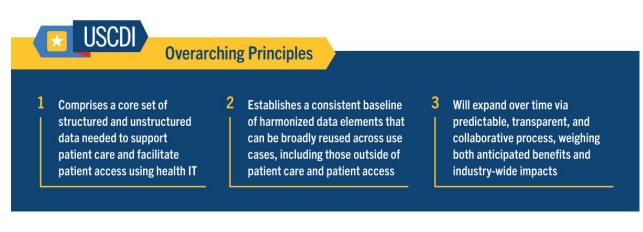
ONC Standards Bulletin 2022-2

ONC Standards Bulletin 2022-2 (SB22-2) discusses the development and finalization of the latest version of the United States Core Data for Interoperability (USCDI), Version 3 (USCDI v3), which was released on July 19, 2022. Stakeholders across the healthcare system benefit from the USCDI, which sets the technical foundation for the access, exchange, and use of electronic health information to support patient care. The USCDI defines the baseline set of data to inform interoperable implementations for stakeholders such as federal agencies supporting health and health care, hospitals, research organizations, clinician offices, and software developers. ONC updates the USCDI annually to keep pace with medical, technology, and policy changes. USCDI v3 includes new data elements that are consistent with the Biden-Harris Administration's Executive Orders on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.

SB22-2 describes ONC's continued expansion of USCDI, including the prioritization approach for USCDI Version 4. This bulletin reflects ONC's consideration of stakeholder feedback and the ONC Health IT Advisory Committee (HITAC) recommendations on Draft USCDI v3 released in January 2022.

United States Core Data for Interoperability Version 3

The USCDI is not static and is intended to expand over time as standards mature and users' needs evolve. With the publication of USCDI v3, the USCDI has expanded from 52 data elements in 16 data classes in v1, to 94 data elements in 19 data classes in v3. Following the publication of Draft USCDI v3 in January 2022, ONC received more than 800 public comments on data classes and elements through HealthIT.gov/USCDI. This feedback included more than 60 letters from organizations representing a wide range of stakeholders. ONC received comments on new data elements in Draft USCDI v3 and other data elements that were not included in Draft v3. In developing the final list of data elements for USCDI v3, ONC applied established prioritization criteria to consider additional data elements beyond what was included in Draft USCDI v3.

Figure 1: USCDI Overarching Principles

Based on the principles above and the established prioritization criteria, the final version of USCDI v3 focuses on promoting equity, reducing disparities, and supporting public health data interoperability as discussed in Standards Bulletin 2021-3. The following two new data classes and 24 new data elements have been added to USCDI v3, including all 20 data elements proposed in Draft USCDI v3 and four additional data elements.

Table 1: New Data Classes and Data Elements in USCDI v3

New Data Class	New Data Class	Laboratory
Health Insurance Information	**Health Status/Assessments**	• Specimen Type
• Coverage Status	• Functional Status	• Result Status
• Coverage Type	• Disability Status	
• Relationship to Subscriber	• Mental/Cognitive Status	
• Member Identifier	• Pregnancy Status	
• Subscriber Identifier		
• Group Number		
• Payer Identifier		
Medications	**Patient Demographics/Information**	**Procedures**
• Dose	• Date of Death	• Reason for Referral
• Dose Unit of Measure	• Tribal Affiliation	
• Indication	• Related Person's Name	
• Fill Status	• Related Person's Relationship	
	• Occupation	
	• Occupation Industry	

What's New in USCDI v3

Building on USCDI v2, USCDI v3 added 24 data elements across the following data classes: *Health Insurance Information, Health Status/Assessments, Laboratory, Medications, Patient Demographics/Information,* and *Procedures.*

Medications Data Elements

ONC received significant input during USCDI v3's public feedback cycle urging ONC to add medication-related data elements to the existing data class in USCDI v3, even though they were not part of Draft USCDI v3. In response to this input, we evaluated level 2 classified data elements and added *Dose, Dose Unit of Measure, Indication*, and *Fill Status* to the *Medications* data class. The additional data elements are necessary for certain CMS reporting programs and are also required elements in ONC certification criteria, including electronic prescribing. Additionally, we added *National Drug Codes (NDC)* as an optional terminology for the *Medications* data element.

Health Status/Assessments Data Elements

USCDI Draft v3 included a new data class, *Health Status*. In response to stakeholder input to make the description/scope of this data class clearer and more representative of the types of data that could be included, USCDI v3 refers to this data class as *Health Status/Assessments*. This new data class represents assessments of health-related matters performed during care that could identify a need or problem. The new data elements in this data class are *Disability Status*, *Mental/Cognitive Status (Mental Status* in Draft v3*)*, *Functional Status*, and *Pregnancy Status*. *Pregnancy Status* is of particular importance to those who provide care for persons who may be or seek to become pregnant. It is also a

substantive data element for lab testing and public health reporting, as noted by ONC's prior federal advisory committees.[i] The *Health Status/Assessments* data class provides a broader context than the USCDI v2 *Health Concerns* data class, therefore we also moved *Health Concerns* into this new data class.

Health Insurance Information Data Elements

USCDI v3 also includes a new data class *Health Insurance Information*, which provides an opportunity for health IT (not just electronic health record systems) to capture and exchange key health care insurance coverage information in a consistent and standardized way. This information can be useful for patient care, and to identify health care disparities related to insurance coverage. This data class includes seven new elements: *Coverage Status*, *Relationship to Subscriber*, *Member Identifier, Subscriber Identifier*, *Payer Identifier, Group Identifier*, and *Coverage Type*. We received feedback that *Coverage Type* may be based on the setting and type of care provided, and we call on stakeholders to identify an applicable vocabulary standard.

Laboratory Data Elements

To address public health reporting priorities, especially those identified during the COVID-19 pandemic, ONC added *Specimen Type* and *Result Status* to the *Laboratory* data class.

Patient Demographics/Information Data Elements

ONC also received feedback that over time data elements in the *Patient Demographics* data class had expanded beyond just purely demographics. To address this feedback, we have changed the data class's name to *Patient Demographics/Information*. In addition to the data class name change and the changes to *Sex, Sexual Orientation, Gender Identity*, and patient addresses discussed below, ONC added seven new data elements to the *Patient Demographics/Information* data class. *Related Person's Name* and *Related Person's Relationship* enable linkages between maternal and child records as well as identifying other related persons, such as custodians and guardians. *Date of Death* supports patient matching, adverse events, public health, and vital records reporting. *Occupation* and *Occupation Industry* were added to support public health, equity concerns, and to capture military service. Finally, *Tribal Affiliation*, is extensively captured by the U.S. Indian Health Service to aid in determination of eligibility for IHS services, care-coordination with non-tribal medical facilities, and identification of disparities in health care in and across tribal populations. The new data elements in *Patient Demographics/Information* also support social and environmental factors that enable person-centered care, research to advance health equity, and social determinants of health.

Procedures Data Element

ONC added *Reason for Referral* to the *Procedure* data class, as this data element is already part of the Certification Program requirements for Transitions of Care and is broadly implemented in health IT. We also clarified through the data class definition and scope that *Reason for Referral* is used in referrals and consultations and is not intended to represent the clinical indication for procedures. This concept is captured by problems or encounter diagnosis.

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[i] https://www.healthit.gov/sites/default/files/facas/HITJC_Public%20Health%20Task%20Force_%20Transmittal%20Letter_508C.docx

Vital Signs Data Element

We also changed the *Vital Signs* data element, *Weight-for-Length Percentile*, from "*Birth – 36 Months*" to "*Birth – 24 Months*." This change reflects input from the standards, clinical, and pediatric health care communities that *Weight-for-Length Percentile* is not used after 24 months of age. *BMI Percentile (2 – 20 Years)* is used after 24 months of age. Changing the age range of *Weight-for-Length Percentile* does not change the way it is used.

Other Updates Within USCDI v3

To address the need for flexibility in the way certain data elements are represented in health IT, and the rapidly changing terminology landscape around these data elements, ONC removed the references to specific value sets and codes. Instead, where appropriate, we replaced these value sets and codes with applicable vocabulary standards and will continue to use the Interoperability Standards Advisory to identify value sets or code sets that may be helpful for developers and implementers. We also updated the applicable vocabulary standards for data elements to their latest published versions and clarified the definitions and scope of many data elements to assist with implementation.

Based on ongoing standards development, we made updates to the definition for *Discharge Summary Note* to include *admission* and *discharge dates* and *locations*, *discharge instructions*, and *reason(s) for admission*. We expect the implementation burden to be minimal because this data is required in the Transitions of Care, and View, Download and Transmit to 3rd Party Certification Criteria.

Addressing Draft USCDI v3 Request for Feedback

When ONC published Draft USCDI v3 in January 2022, we asked the public to provide feedback on several existing data elements in USCDI, namely *Sex (Assigned at Birth)*, *Gender Identity*, and *Current* and *Previous Address*. We did this because newer terminology standards, definitions, and concepts have been identified by stakeholders. Multiple stakeholders including the HL7 Gender Harmony Project recognized that the data element *Sex (Assigned at Birth)* is used to represent different concepts not necessarily associated with what is assigned at the time of birth, such as clinically relevant sex for labs or diagnostic imaging, as well as administrative sex as recorded on birth certificates and health forms. The values used for each instance may not be the same for a given patient. Furthermore, the value set ONC has used for this data element does not include all possible values that represent sex. We therefore removed the reference to the limited value set previously used and expanded the applicable vocabulary standard to the SNOMED CT code set. We also changed the name of this data element to *Sex* to recognize that its use is not limited to just what is documented at birth.

The data elements *Sexual Orientation* and *Gender Identity* posed similar issues in that the applicable static value sets ONC defined in the 2015 Certification Rule and has used for USCDI since its initial adoption no longer reflect current social norms and clinical practice. The HL7 Gender Harmony Project and other stakeholders provided feedback that these value sets are limited and don't accurately represent the sexual orientations and gender identities a patient may state. As new concepts are being identified and new codes developed, more flexibility in how these concepts are captured in health IT becomes paramount. Therefore, ONC removed the references to these value sets in USCDI v3 and replaced them with the broader SNOMED CT code set. Additional codes may need to be developed to meet various stakeholders needs, and SNOMED CT provides a well-established system of expansion.

The HL7 Gender Harmony Project developed two data elements, *Recorded Sex or Gender (RSoG)* and *Sex for Clinical Use (SFCU)* to represent the administrative and clinical uses for *Sex*, respectively, and has recently developed standards supporting their use and implementation in health IT. In addition, *Name to Use* and *Pronouns* have been defined to facilitate culturally competent care and can be used to document how a patient chooses to be addressed by their health care team. ONC recognizes the value of the elements defined by the HL7 Gender Harmony Project but determined that these standardized approaches are not yet mature nor adopted widely enough to warrant inclusion in USCDI v3. We anticipate the growing use and implementation of these elements will allow for consideration to be included in a future USCDI version.

ONC encourages health IT developers to enable collection of data that meet USCDI priorities. For example, collection of *SFCU, RSoG*, *Name to Use*, and *Pronouns* provide benefit to the Lesbian, Gay, Bisexual, Transgender, Questioning, Intersex, and Asexual (LGBTQIA+) communities.

We also requested input on *Current Address* and *Previous Address* and whether ONC should use the new [Project US@](#) Technical Specification for Patient Addresses Final Version 1.0 as the applicable standard. US@ is a result of collaboration across standards development organizations and other stakeholders to develop the technical specification and a companion guide for patient address standardization. ONC received a significant amount of support for this and has defined US@ as the applicable vocabulary standard for *Current Address* and *Previous Address* in the *Patient Demographics/Information* data class. We believe this new standard will advance the quality and safety of patient addresses and has the potential for use in other address-related data elements in the future.

USCDI v4 Submission Period

ONC is now accepting new submissions for data classes and data elements to be considered for inclusion in the next version of USCDI, Version 4 (USCDI v4). After reviewing the USCDI website for data classes and elements that may already meet their needs, anyone can submit new data classes or elements using the [ONC New Data Element and Class Submission System (ONDEC)](#). Submitters can see how ONC evaluates new submissions using the [USCDI ONDEC Submission Prep Sheet](#) as a guide. ONC evaluates all submissions based on [published leveling criteria](#) and notifies submitters of the level of technical maturity (Comment, Level 1, or Level 2) their submissions received or if any additional information is needed. **The submission period for USCDI v4 ends Friday, September 30, 2022, at 11:59pm ET.**

ONC encourages stakeholders to engage and collaborate to submit comments and additional information for data elements previously submitted that are not included in USCDI v3. Additional information provided by commenters may lead to some data elements being promoted to a higher level of maturity and readiness (Level 1 or Level 2) and consideration by ONC for inclusion in USCDI v4 or future versions.

ONC intends to use the following prioritization criteria for Level 2 data elements to help inform Draft USCDI v4 selections.

USCDI Prioritization Criteria

- Represent important additions over previous USCDI versions
- Mitigate health and health care inequities and disparities
- Address the needs of underserved communities
- Address behavioral health integration with primary care and other physical care
- Address public health interoperability needs of reporting, investigation, and emergency response
- Require only modest standards or implementation guide developmental burden
- Require only modest developmental burden on health IT modules
- Create only modest implementation burden on providers and health systems
- Result in only modest aggregate lift for all new data elements combined

ONC plans to publish Draft USCDI Version 4 in January 2023. This will kick off the annual feedback cycle that includes input from the HITAC and other public stakeholders. ONC will take this feedback into consideration before finalizing USCDI v4 in July 2023.