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ONC HEALTH IT STANDARDS BULLETIN

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ONC Standards Bulletin 2021-3

The ONC Standards Bulletin 2021-3 (SB21-3) discusses the release of the [United States Core Data for Interoperability Version 2 \(USCDI v2\)](#), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The vast majority of clinicians and hospitals in the U.S. use health information technology (health IT), including electronic health records, certified by ONC's Health IT Certification Program, which will require the use of USCDI Version 1 starting next year. Consistent with the Biden Administration's executive orders, new data elements have been included in USCDI v2 to support the Administration's efforts to advance health equity, including data elements for sexual orientation, gender identity, and social determinants of health.

SB21-3 describes ONC's vision for the future expansion of [USCDI](#), including the prioritization approach that will be used for USCDI Version 3. It reflects ONC's consideration and incorporation of stakeholder feedback and the [ONC Health IT Advisory Committee \(HITAC\)](#) recommendations on draft USCDI v2.



United States Core Data for Interoperability Version 2

The USCDI is not static, it is intended to grow over time as standards mature and users' needs evolve. In 2020, ONC initiated a process to gather submissions from the public and healthcare community at large on new data classes and data elements for USCDI v2. ONC received several hundred submissions through the [ONC New Data Element and Class \(ONDEC\)](#) submission system. ONC used [published evaluation criteria](#) to classify each submitted data element into one of three levels (Comment, Level 1, or Level 2) based on the overall value, maturity, and known challenges to implementation. ONC classified more than 100 data element submissions as Level 2 and, thus, eligible to be considered for inclusion in USCDI v2.

ONC prioritized data elements that would give the highest return on effort: were of industry importance, required minimal standards development (e.g., updates to Health Level Seven (HL7®) [Fast Healthcare Interoperable Resources \(FHIR®\) US Core](#) and [Consolidated Clinical Document Architecture \(C-CDA\)](#) implementation guides), and minimal burden on health IT developers, implementing health professionals, and health systems.

As a result, ONC published the [Draft USCDI v2](#) in January 2021, which included two new data classes and nine new data elements. ONC received extensive feedback from the HITAC and the public on the Draft USCDI v2, as well as feedback on many data elements and classes that were not included. Consistent with the Administration's goals to assess and identify opportunities to advance equity and support for underserved communities, ONC evaluated USCDI v2's scope as part of its finalization process to look at places where including specific data elements could help advance the use of health information technology to support health equity. The collection, access, use, and reporting of standardized social determinants of health (SDOH) as well as sexual orientation and gender identity data can help identify and address differences in health equity and improve health outcomes at an individual and population level.ⁱ

For the final version of USCDI Version 2, ONC has included three new data classes and 22 new data elements as illustrated in the grid below. Among the 22 new data elements are four SDOH data elements as well as data elements for sexual orientation and gender identity.

ⁱ [Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation](#)

New Data Classes and Elements in USCDI v2

<p>Assessment and Plan of Treatment</p> <ul style="list-style-type: none"> • SDOH Assessment 	<p>Care Team Member(s)</p> <ul style="list-style-type: none"> • Care Team Member Name • Care Team Member Identifier • Care Team Member Location • Care Team Member Telecom • Care Team Member Role 	<p>New Data Class & Elements</p> <p>Clinical Tests</p> <ul style="list-style-type: none"> • Clinical Test • Clinical Test Result/Report
<p>New Data Class & Elements</p> <p>Diagnostic Imaging</p> <ul style="list-style-type: none"> • Diagnostic Imaging Test • Diagnostic Imaging Report 	<p>New Data Class & Elements</p> <p>Encounter Information</p> <ul style="list-style-type: none"> • Encounter Diagnosis • Encounter Disposition • Encounter Location • Encounter Time • Encounter Type 	<p>Goals</p> <ul style="list-style-type: none"> • SDOH Goals
<p>Patient Demographics</p> <ul style="list-style-type: none"> • Gender Identity • Sexual Orientation 	<p>Problems</p> <ul style="list-style-type: none"> • SDOH Problems/Health Concerns • Date of Diagnosis • Date of Resolution 	<p>Procedures</p> <ul style="list-style-type: none"> • SDOH Interventions

USCDI v2 Health Equity Highlights

In 2015, as part of ONC’s 2015 Edition Final Rule, ONC included a requirement that health IT certified to the “demographics” certification criterion (45 CFR 170.315(a)(5)) needed to be capable of recording standardized data on a patient’s sexual orientation and gender identity (SOGI). Health IT certified to this certification criterion is now widely deployed among hospitals and ambulatory providers. These SOGI data, however, were not included as part of the Common Clinical Data Set in 2015. As a result, health IT was not required, for example, to demonstrate that it could include SOGI data as part of summary care records created pursuant to the “transitions of care” certification criterion. By including these two data elements in USCDI v2, the ability to exchange them to support safe, coordinated care will now come into focus.

Similarly, we added four SDOH data elements to enable identification of specific needs in domains such as food, housing, and transportation insecurity, and to coordinate care and assistance to improve health outcomes. Each of these data elements represents a specific aspect of these domains of SDOH care. As the [Gravity Project](#) and the standards development community add content in these and other domains, these data elements will provide a predictable way to represent this information in USCDI.

The new SDOH data elements in USCDI v2 have been placed into applicable, existing data classes as represented below:

Existing USCDI Data Class	New Data Element
Assessment and Plan of Treatment	SDOH Assessment
Goals	SDOH Goals
Procedures	SDOH Interventions
Problems	SDOH Problems/Health Concerns

In the near term, including the SDOH and SOGI data elements in USCDI v2 puts these data elements (along with all others in USCDI v2) on the path to be considered in this year’s voluntary standards version advancement process (SVAP) and to be a part of ONC’s regulatory proposals in the future.

Additional Changes to USCDI v2

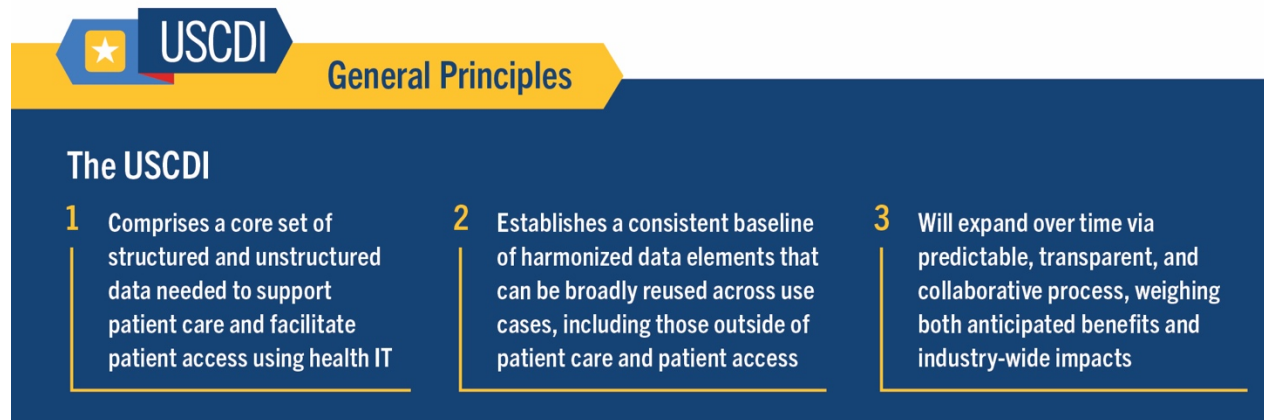
The USCDI v2 includes three new data classes and associated new data elements: 1) Clinical Tests; 2) Diagnostic Imaging; and 3) Encounter Information. The Clinical Tests and Diagnostic Imaging data classes represent tests performed on a patient to aid in the diagnosis or management of conditions. The Encounter Information data class represents information about individual episodes of care. Data elements were also added to the Care Team Members and Problems data classes to provide more detailed information for each class.

Reflecting feedback regarding the hybrid way in which clinical problems are recorded and represented in health IT in the field, the USCDI v2 reflects the flexibility to use either SNOMED CT (currently required in USCDI v1) or ICD-10-CM. We also updated all the clinical vocabulary “minimum standards” code sets to the most recent published versions.

ONC also removed three data elements that were part of the USCDI v1 Clinical Notes data class but considered redundant: Imaging Narrative, Laboratory Report Narrative, and Pathology Report Narrative. These data elements were originally intended to convey valuable narrative context related to their respective test results. The narrative components of these data elements have been incorporated into Diagnostic Imaging Report and Laboratory Values/Results data elements in USCDI v2.

USCDI Principles, Future Expansion, and Relationship to Other Initiatives

As part of ONC's long-term stewardship of the USCDI, we have adopted the following general principles to describe what the USCDI is, its focus, and how ONC will approach its expansion over time.



The graphic features a blue header with a yellow star icon and the text 'USCDI' in white. Below this, a yellow banner contains the text 'General Principles'. The main content area is dark blue and contains three numbered points, each enclosed in a yellow-bordered box.

The USCDI

- 1 Comprises a core set of structured and unstructured data needed to support patient care and facilitate patient access using health IT
- 2 Establishes a consistent baseline of harmonized data elements that can be broadly reused across use cases, including those outside of patient care and patient access
- 3 Will expand over time via predictable, transparent, and collaborative process, weighing both anticipated benefits and industry-wide impacts

ONC expects each USCDI version to grow incrementally. As a result, the USCDI is best viewed as a “floor” that rises with each published version and that strengthens the foundation of reliably available and consistently specified structured and unstructured data for different interoperability needs. Whether a use case requires just a few data elements from the USCDI or all of them and more, the USCDI establishes a way for the industry to quickly reach alignment on shared data elements.

However, we recognize that the USCDI's focused scope and incremental expansion means that will not always be able to support the entirety of the data needs for a given use case (e.g., a research study, specialty care). Accordingly, ONC has started to explore approaches that can support partners who would like to use USCDI plus additional data elements to extend beyond the USCDI's scope in way that makes it clear how such additional data complements and relates to the USCDI.

It's Time to Prepare for USCDI v3

ONC is currently accepting new submissions for data elements and data classes to be considered for inclusion in the next version of USCDI, Version 3 (USCDI v3). 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 ONDEC. ONC also encourages stakeholders to engage and collaborate with other submitters on new data elements, which may result in a data element being classified at a higher level (e.g., up to Level 2 from Level 1 in ONDEC) and a higher priority for addition to the next version of USCDI.

Help Make an Impact

Collaborate via
[HealthIT.gov/isa/ONDEC](https://healthit.gov/isa/ONDEC)

The criteria ONC uses to evaluate submitted data elements can be reviewed by consulting the [USCDI ONDEC Submission Prep Sheet](#). ONC will review all submissions and notify submitters on how their submissions were classified or if any additional information is needed. **The submission period for USCDI v3 ends Thursday, September 30, 2021 at 11:59pm ET.** Please see our prioritization approach for USCDI v3 below.

ONC is putting forward updated prioritization criteria we will use to consider and select among all Level 2 data elements (both existing and newly submitted) for inclusion in USCDI v3. This is intended to assist in the planning for the development and submission of new data classes and elements and to encourage the submission of new data classes and elements in alignment with key national healthcare goals.

ONC will continue to look to give priority to Level 2 data classes and elements that

- Represent important additions over USCDI v2.
- 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 will continue to work with the public and federal agencies to identify gaps and highlight areas where more work is needed to be included in future versions of the USCDI. This will support stakeholders in their efforts to identify opportunities to collaborate with others to mature these data elements or to prepare submissions that address these highlighted areas.

Version 3 Areas of Focus

As part of our effort to advance equity and support for underserved communities, ONC will consider the following focus areas for priority inclusion in USCDI v3

1. Mitigating health and healthcare inequities and disparities.
2. Addressing the needs of underserved communities.
3. Addressing public health reporting, investigation, and emergency response.

ONC plans to publish Draft USCDI Version 3 in January 2022. This will kick off the annual feedback cycle and will include input from the HITAC and other public stakeholders. ONC will take this feedback into consideration as we finalize USCDI v3 in July 2022.