



ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

April 15, 2021

**ASSOCIATION CHAIR
OF THE BOARD**

Monica M. Bertagnoli, MD,
FACS, FASCO

ASSOCIATION TREASURER

Eric J. Small, MD, FASCO

ASSOCIATION DIRECTORS

Howard A. "Skip" Burris, III, MD,
FACP, FASCO

Laurie E. Gaspar, MD, MBA,
FASTRO, FACR, FASCO

Carolyn B. Hendricks, MD, FASCO

Reshma Jagsi, MD, DPhil,
FASTRO, FASCO

Michael P. Kosty, MD,
FACP, FASCO

Kurt R. Oettel, MD

Lori J. Pierce, MD,
FASTRO, FASCO

Everett E. Vokes, MD, FASCO

NON-VOTING DIRECTOR

Chief Executive Officer

Clifford A. Hudis, MD,
FACP, FASCO

Dr. Micky Tripathi
National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20201

RE: Draft US Core Data for Interoperability, Version 2 (USCDI v2)

**Submitted electronically via the ONC portal at
<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#comment-form>**

Dear Dr. Tripathi,

We appreciate the opportunity to comment on the Draft US Core Data for Interoperability, Version 2 (USCDI v2). The Association for Clinical Oncology (the Association) is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

In August 2020, our affiliate organization, the American Society of Clinical Oncology (the Society) issued a formal policy statement¹ on cancer disparities and health equity calling for bolder, more aggressive steps to achieve equity for all patients. Focusing broadly on four areas including ensuring equitable access to high-quality care; ensuring equitable access to research; addressing structural barriers to equitable care; and increasing awareness and action, this statement serves as our blueprint for achieving health equity in cancer care.

The achievement of equity requires broad approaches, which include addressing social determinants of health (SDOH), and the capacity for structured electronic exchange of SDOH is essential to this effort. The capture and sharing of this data can assist in identifying strategies to address the SDOH which is crucial to reducing disparities and understanding the role of SDOH on cancer care and outcomes.

¹ Cancer Disparities and Health Equity: A Policy Statement from the American Society of Clinical Oncology Manali I. Patel, Ana Maria Lopez, William Blackstock, Katherine Reeder-Hayes, E. Allyn Moushey, Jonathan Phillips, and William Tap. Journal of Clinical Oncology 2020 38:29, 3439-3448.

In the Draft USCDI v2, data elements/classes that have been proposed for use to capture data on social determinants of health (SDOH)² are currently classified as “Level 2.” Level 2³ data elements are represented by health care standard terminology or implementation specifications such as HL7® FHIR® 4 and demonstrate extensive existing use in systems and exchange between systems and use cases that show significant value to current and potential users. According to ONC, Level 2 data elements would clearly improve nationwide interoperability. However, while ONC prioritized certain Level 2 data elements for inclusion in the Draft USCDI v2, SDOH was not included.

We encourage ONC to prioritize the SDOH data elements/classes for inclusion in USCDI v2. Placement of these data elements/classes into USCDI v2 would allow documentation and exchange of SDOH data related to (1) assessments of risks, (2) the declaration of problems/health concerns, problems, and diagnoses, (3) the establishment of specific goals, (4) the identification of interventions, (5) tracking outcomes, and (6) recording and exchanging consent, where needed, to share the SDOH-related data. One note of caution we would like to express regarding the standards proposed here involves the use of LOINC; we would recommend that it is best to standardize on a single ontology-based coding system such as SNOMED.

The following SDOH domains are included: (1) Food Insecurity, (2) Housing Instability and Homelessness, (3) Inadequate Housing, (4) Transportation Insecurity, (5), Financial Strain, (6) Social Isolation, (7) Stress, (8) Interpersonal Violence, (9) Education, (10) Employment, and (11) Veteran Status, in conjunction with the patient encounter. We note that many other SDOH domains/data elements are also included at the Comment Level and we recognize that going forward there will be opportunity both for refinement of initially chosen elements and for addition of new elements.

The capture of the data described above is critical to identifying and addressing the impact of SDOH on all patients, including cancer patients, who often suffer disproportionately from “financial toxicity.” This information is often collected across providers caring for the same patient but is stored in unstructured fields where it is usually not shared across and among these providers, leading to potential gaps in patient care and repetitive redocumentation. Structuring of this data will lead to better documentation of individual patient needs and concerns and will help track interventions and patient outcomes. It can also aid in population health by identifying potential health disparities among patient populations and by helping to direct resources to services shown to have a positive impact on patient outcomes.

Looking ahead to the implementation of these elements, we note that capture and recording of this information should not be limited to physicians but should include other members of the care team. Future measurement of these elements—quality, cost, outcomes—is likely most informative at the health-system level.

² SDOH was submitted by The Gravity Project, a national public collaborative that develops consensus-based data standards to improve the use and sharing of information on social determinants of health (SDOH) and is an HL7 FHIR Accelerator.

³ A data element designated as “Comment” level is represented by health care standard terminology such as SNOMED CT® or implementation specifications such as HL7® FHIR® 4. In addition to “Comment” level criteria, Level 1 data elements demonstrate limited existing use in electronic systems, limited exchange between systems and more well-defined use cases and value to potential users. There may still be some burdens associated with development and implementation. In addition to “Comment” and “Level 1” criteria, Level 2 data elements demonstrate extensive existing use in systems and exchange between systems and use cases that show significant value to current and potential users. These data elements would clearly improve nationwide interoperability.

* * * * *

Concurrently during this USCDI submission cycle, our affiliate organization (the Society), along with MITRE and the mCODE® Initiative Collaborators submitted a proposal for new mCODE (“Minimal Common Oncology Data Elements) data elements to be added to the USCDI. The mCODE Initiative is governed by the mCODE Executive Committee, a group of public and private entities who have voluntarily come together to further mCODE adoption. Members include The Alliance for Clinical Trials in Oncology Foundation; the American Society of Clinical Oncology, and its nonprofit subsidiary, CancerLinQ LLC; The MITRE Corporation; The American Society for Radiation Oncology (ASTRO); and the Society of Surgical Oncology.⁴

mCODE is a focused set of data elements developed by a collaboration of oncology experts. These data elements were selected based on their broad applicability to cancer patients and survivors and to support a variety of cancer care and research applications across a variety of cancer types. As a Health Level 7 (HL7) Standard for Trial Use (STU) these elements were refined with broad input and review through the HL7 ballot; they are currently being tested through several implementation use cases managed through the CodeX™ HL7 FHIR Accelerator™.⁵ For this initial submission to the ONDEC, the mCODE Collaboration submitted elements that have both reached consensus within the oncology and HL7 communities and are also applicable to disease areas beyond oncology.

The data classes and elements submitted included: patient (date of death/deceased); problem (disease trend, disease stage/staging system); assessment and plan of treatment (functional status, treatment change); and procedures/medications (treatment intent). Most of these elements were placed by ONC on the USCDI v2 “Comment Level,” indicating the agency’s judgment that these elements may not have a well-defined use case or value to potential users and that there may be significant or unknown burdens associated with development or implementation. However, treatment intent associated with medications was placed on Level 1 and a version of “deceased” submitted by a different organization was placed on Level 2.

We understand that the updating of the USCDI is an iterative process and appreciate the opportunity to submit data elements/classes for ONC’s consideration. Currently, many organizations are collaborating on pilots to enable, test, and advance mCODE use; as noted above, several of these activities are being coordinated through the CodeX HL7 FHIR Accelerator. As we have previously emphasized to ONC, the ongoing need for structured oncology data is critical. Broad application and use of these data elements will provide critical insights necessary to addressing the persistent barriers to achieving high quality—and equitable—care for every patient. Moreover, adoption of mCODE (or a subset) into USCDI would improve data capture for electronic reporting of oncology quality measures in the Center for Medicare and Medicaid Services’ (CMS) Merit-based Incentive Payment System (MIPS) and could help to support CMS priorities such as the Center for Medicare and Medicaid Innovation’s (CMMI) Radiation Oncology mandatory payment model. CMMI is requiring the collection of certain specific “clinical data elements” (CDEs) from participants in the RO model scheduled to begin in January 2022. Incorporation of standard cancer data classes and elements into the USCDI and certified EHRs by ONC could ultimately help CMS to standardize data collection and decrease reporting burden, benefiting both patients and providers.

⁴ Available at <https://mcodeinitiative.org/collaborators/>

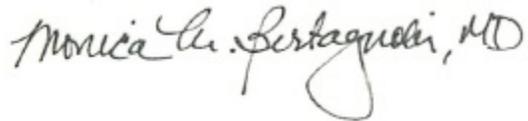
⁵ More information available at <https://confluence.hl7.org/display/COD/CodeX+Home>

We look forward to working with ONC to secure placement of meaningful oncology data elements into the USCDI going forward.

* * * * *

We appreciate the opportunity to provide comments on the Draft USCDI v2. For additional information or any questions, please contact Karen Hagerty (karen.hagerty@asco.org).

Sincerely,

A handwritten signature in black ink that reads "Monica M. Bertagnolli, MD". The signature is written in a cursive style with a large, looped initial 'M'.

Monica M. Bertagnolli, MD, FACS, FASCO

Chair of the Board, ASCO Association for Clinical Oncology