



April 17, 2023

The Honorable Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW; Floor 7
Washington, DC 20201

Re: United States Core Data for Interoperability (USCDI) v4; comments for consideration

Comments submitted electronically

Dear National Coordinator Tripathi:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the draft USCDI v4 data elements and classes. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA appreciates ONC's efforts to solicit feedback on data collection for future iterations of USCDI. Overall, AMIA encourages ONC to ensure that USCDI will decrease burden with common elements for interoperable exchange. Increasing burden on clinical workflow will be a detriment to all stakeholders. We believe the lack of clear definition of certain data classes and elements will add to burden. Notably, we recognize the overarching challenge to craft this common data set to be equally credible, electronically consumable, and useful to patients, providers and payers alike.

AMIA offers the following comments on specific data classes and elements:

- Clinical Notes - Data quality is fundamental to meaningful interpretation of care notes. Included provenance should disclose when "notes" are generated from pick lists or which have been copied/pasted from another source. This standard assists tracking the clinical notes journey and how they are completed by the care team. Certain electronic health records management systems track the percentage of clinical notes that are copied/pasted.
- Disability Status – AMIA suggests that Disability Status, under Health Status/Assessments, be moved to Patient Demographics/Information. The disability community on the whole has argued that questions to assess disability should be addressed to everyone; they should not single out some people for a report as part of health status.
- Encounter Information – With reference to the Primary Encounter diagnosis field, AMIA encourages ONC to replace “diagnosis” with “diagnoses.”
- Goals – This data class is defined as “desired state to be achieved by a patient.” AMIA encourages ONC to consider renaming this category to “Person Goals and Preferences.” Person-centric goals reflect goals over time, not just when the person is a patient. AMIA continues to believe that “goals” should be defined and differentiated (i.e.: person-defined or generated, clinician-captured, obtained through interdisciplinary team members such as care coordinators or social workers, or goals from clinician orders or advanced care planning documents). Identifying the source of the information in this data class is central to interpreting the outputs. For example, the desired goal or outcome stated by the person and captured directly from the person, may or may not have the same perceived value as goals captured from submitted advanced care planning documents or prior clinician orders. There are increasingly structured and validated ways to capture goal setting. The National Committee for Quality Assurance has developed outcome measurements with the patient central to the research.¹ NCQA AMIA suggests to align with emerging standards in this area as we have seen organizations have success – for example – say that having an advanced directive counts for this.

¹ <https://www.ncqa.org/hedis/reports-and-research/pco-measures/>

- Health Status Assessment – There is a need to recognize that the burden of data collection falls on the end-user clinician. Data should be derivative of the clinical workflow. There is a need to recognize that the burden of data collection falls on the end-user clinician. Data should be derivative of the clinical workflow. There is a need to limit the burden of data collection that falls on the end-user clinician, as excess documentation burden can compromise data quality and overall patient care. As standards change and evolve, AMIA encourages routine updates and alignment with HL7 FHIR Accelerator, The Gravity Project.
- Medications - medication reconciliation is a notorious problem and documentation of medication adherence is corollary to that problem. Fill history may be available from some pharmacies as a measure of adherence, but whether the patient is actually taking the medication is largely based on patient self-reporting. We question whether Medication Adherence is a useful addition given reliance on patient self-reporting.
- Patient Demographics Information – AMIA encourages ONC to ensure that vocabulary standards are updated routinely as standards change and evolve, to avoid stigmatizing language and ensure health equity and respect for all people.
- Problems – There are limitations on the capture of diagnosis information. The problem or reason for seeking medical attention is often not documented in the health record. In reality, “Actual Date of Diagnosis” and “Date of Resolution” are typically not known, or are captured without adequate context to determine accuracy. These elements are included but may not yield any accurate information.
- Provenance - The information contained in this data class is a critical underpinning for all other data classes and elements. Beyond the elements of author time stamp and author organization, the role of the author should be identified. The author may or may not be an identified member of the care team, especially highlighting the possibility of patients and authorized family or caregivers as potential contributors of health data. The author may also be health devices, mobile health applications and remote patient monitoring devices or sensors (e.g., in home, body worn). AMIA recommends potentially creating role buckets, or groupings, such as “patient/caregiver, device, or health system employee/contractor/affiliate” understanding there are not standards to define roles.
- Vital Signs - ONC should consider adding elements to identify the role of the individual taking the vital signs, differentiating between inputs that might be from a care team

member, or patient or family/caregiver, as separate from an automated device or home monitoring system.

- AMIA suggests that ONC add “Participation in Clinical Trials” as a data class for inclusion in USCDIv4. It is necessary to capture the unique clinical scenarios of participants enrolled in clinical research studies.
- ONC should continue to work with HL7 to ensure that USCDI elements map to corresponding FHIR Resources.

AMIA would be pleased to serve as a resource to ONC as it continues its important work to advance meaningful data collection. Thank you for your time and consideration of these comments. If you have questions or require additional information, please contact Tayler Williams, AMIA Public Policy Manager, at twilliams@amia.org

Sincerely,

A handwritten signature in blue ink that reads "Gretchen P Jackson". The signature is written in a cursive, flowing style.

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
President and Board Chair, AMIA
Vice President & Scientific Medical Officer, Intuitive Surgical
Associate Professor of Surgery, Pediatrics, and Biomedical Informatics, Vanderbilt University
Medical Center