April 12, 2024

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi?check_logged_in=1#comment-form

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 5

Dear Dr. Tripathi:

The Regenstrief Institute welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability (USCDI) Version 5 and related data classes standards and elements. The Regenstrief Institute is a local, national, and global leader with a vision to provide pioneering transformative, interdisciplinary solutions for a healthier and more equitable world. A key research partner to Indiana University, Regenstrief and its research scientists are responsible for a growing number of major healthcare innovations and studies. Regenstrief is also the steward for vocabulary standards Logical Observations Identifiers Names and Codes (LOINC®) and The Unified Code for Units of Measure (UCUM). A key part of our mission is to develop and advance the adoption of data standards that enable efficient transmission, understanding, and use of health data.

Our comments for USCDI v5 (summarized on pages 2-9), are intended to augment the USCDI with critical input and support its use in facilitating information exchange and interoperability goals.

If there are questions regarding our comments, please contact Marjorie Rallins, DPM, MS, Executive Director, Health Data Standards at mrallins@regenstrief.org or 317-274-9415.

We appreciate and look forward to continued collaboration with ONC.

Sincerely,

Rachel Patzer, PhD, MPH

President and CEO, Regenstrief Institute

Regenstrief Institute response summary

Office of the National Coordinator for Health Information Technology (ONC)

United States Core Data for Interoperability (USCDI) Standard (Draft Version 5)

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi?check_logged_in=1#comment-form

Comments on USCDI v5 New Data Elements

Data Class: Clinical Notes
Data Element: Emergency Department Note
Comment: The Regenstrief Institute supports the inclusion of the "Emergency Department Note" data element. To specify all components of an Emergency Department Note such as the History and Physical, a focused SOAP note and a discharge summary to include discharge instructions. We recommend use of the LOINC code 34111-5: Emergency Department Note and LOINC Emergency Department group code LG41825-7

Data Class: Clinical Notes
Data Element: Operative Note
Comment: The Regenstrief Institute supports inclusion of "Operative Note" and the use of LOINC terminology. We recommend that an Operative Note include: - The date and time (24-hour clock) - The operation performed, including the side (right or left), specific location, type of anesthesia (general or local), and whether it was an emergency or an elective procedure. - The names of the surgeons, anesthetists, and assistants including their roles and details of supervision (for example, surgeon A—mobilization of colon) - Note the details of the patient's preparation, including positioning (for example, prone), additional procedures (for example, catheterization) and prophylaxis (for example, antibiotics, heparin) - A full description of the operation (based on the template I, F, P, and C) - Incision type (for example, midline) - Findings. This should include the pathology discovered during the operation and other unexpected findings, such as anatomical variations. - Procedure. A step-by-step documentation of the operation should be noted, including major structures preserved, techniques used, intraoperative radiological images and microbiological specimens taken. Diagrams are useful especially in complex operations. Document tissue or bodily fluids removed (such as blood loss), the type,

size, and serial numbers of prosthesis and sutures used, closure technique (including type of dressings used)
- Postoperative instructions
- Name, grade, and signature of person writing the operative note

Data Class: Immunizations

Data Element: Lot Number

Comment: The Regenstrief Institute supports the inclusion of the "Lot Number" data element. LOINC provides a placeholder for lot number to be stored in a system. It is very important to include this data element because it allows users to track every single ampoule, bottle, infusion bad, etc. back to manufacturers with the batch that the lot number came from. This will allow quick tracing in case of bad product whether individual or big batch.

We recommend the use of LOINC code: 30959-1 Lot number [Identifier] Vaccine.

Data Class: Laboratory

Data Element: Test Kit Unique Device Identifier

Comment: The Regenstrief Institute has identified several barriers to the implementation of the "Test Kit Unique Device Identifier" data element. The infrastructure in the Laboratory Information Systems and at the lab level is not yet in place to make this feasible. There may be more than one UDI associated with a test result (e.g., kit, control, instrument). Not all results are associated with a kit that has a UDI (e.g., FDA exempt reagents, Lab developed tests).

Data Class: Medications

Data Element: Route

Comment: The Regenstrief Institute supports the inclusion of the medication "Route" data element. In addition to SNOMED CT, we recommend the use of LOINC code: 45373-8 Medication route [Identifier] of Dose.

Data Class: Observations

Data Element: Advanced Directive Observation

Comment: The Regenstrief Institute supports the inclusion of the "Advanced Directive Observation" data element.

We recommend the use of LOINC code: 42348-3 Advanced Directive. The LOINC code supports semantic interoperability by applying the LOINC Document Ontology as the standard, which will have an equivalency in SNOMED CT.

Data Class: Observation

Data Element: Sex Parameter Observation
Comment: The Regenstrief Institute supports the addition of "Sex Parameter Observation" for clinical use. This will support the HL7 Gender Harmony Project. We recommend the use of LOINC code: 99501-9 Sex Parameter for Clinical Use.

Data Class: Orders
Data Element: Orders
Comment: The Regenstrief Institute supports the additions of the "Orders" data element. We recommend that the implementation of this data element include an indication of the order type. Orders are service requests used by clinicians and providers as part of the quality measurements. For example, currently, CMS quality measures include the following order concepts: • Labs and diagnostic studies; • Interventions (i.e. hospice, comfort care, palliative care) and procedures • Devices; • Follow-ups/referrals; • Immunizations: influenza, pneumococcal, and human papilloma virus; • Routine labs for chronic disease monitoring: diabetes, hypertension, and hypothyroidism; • Point of care testing: rapid strep test, urine dip, and urine pregnancy; • A signed order or requisition by the physician for a specific test; • Annotation in the patient's medical record documenting the need for or the intent to obtain a specific test.

Data Class: Patient Demographic Information
Data Element: Name to Use
Comment: The Regenstrief Institute supports the inclusion of the "Name to Use" data element. Availability of this data indicates patient preferences and facilitates patient engagement. We recommend the use of LOINC code: 54125-0 Patient Health Questionnaire.

Data Class: Patient Demographic Information
Data Element: Pronoun
Comment: The Regenstrief Institute supports the inclusion of the "Pronoun" data element. Availability of this data indicates patient preferences, facilitates patient engagement and standardizes data elements related to social care.

We recommend the use of LOINC code 90778-2 Personal Pronouns - Reported. This supports the HL7 Gender Harmony Project.

Data Class: Patient Demographic Information

Data Element: Interpreter Needed

Comment: The Regenstrief Institute supports the addition of the "Interpreter Needed" data element. Availability of this data indicates patient preferences, facilitates patient engagement and standardizes data elements related to social care.

We recommend the use of LOINC code 54588-9 Interpreter Needed.

Comments on USCDI Level 2 Data Elements

Data Class: Clinical Notes

Data Element: Antepartum Summary Note

Comment: The Regenstrief Institute supports the inclusion of the "Antepartum Summary Note". Existing clinical notes do not specify antepartum data that are required to be exchanged to support safe and effective clinical care. Examples of antepartum specific clinical data include:

- Interval medical history since delivery
- Physical and pelvic examination information
- Review of newborn status
- Discussion of birth control options
- Depression and intimate partner violence screenings
- Maternal related immunization review
- Counseling regarding any future pregnancies
- Maternal related interventional education
- Maternal related screenings
- Maternal related interventional tests and results including laboratory, radiology, etc.

According to the 2021 Aspen Health Strategy Group report on "Reversing the U.S. Maternal Mortality Crisis", 700 women die each year as the result of pregnancy or delivery complications, and 50,000 more face short-term or long-term health consequences because of pregnancy or labor. The U.S. has the highest maternal mortality rate of any high-income nation in the world (17.4 maternal deaths per 100,000 live births) according to The Commonwealth Fund. While rates of maternal mortality have been decreasing in other countries, they have been rising in the United States since 1987. Maternal health data is not uniformly standardized, and data exchange is not consistent across many settings, which impedes care and research on maternal morbidity, longitudinal maternal care, and associated impacts to infant and infant health.

Use Cases

The United States Congress S.796 - Protecting Moms Who Served Act of 2021 includes support by the Department of Veterans Affairs for Maternity Care Coordination by carrying out the maternity care coordination program described in the Veterans Health Administration Directive 1330.03. The Veterans Health Administration Directive includes required coordination of maternity care including provision of care across settings.

The 2006 Independent Health Record Bank Act https://www.congress.gov/bill/109th-congress/house-bill/5559?s=1&r=5 describes the following example types of data for inclusion in patient generated records related to antepartum care:

- Encounter data,
- Labs,
- Vital signs,
- Birth directives
- Birth plans
- SDOH assessments or screenings and associated interventions
- Self-Reported biometrics
- Activities of daily living

Data Class: Clinical Notes
Data Element: Postpartum Summary Note
Comment: The Regenstrief Institute recommends the inclusion of the "Postpartum Summary Note". Existing clinical notes do not specify the postpartum data that are required to be exchanged to support safe and effective clinical care.Examples of postpartum specific clinical data includes: • Interval medical history since delivery • Physical and pelvic examination information • Review of newborn status. Maternal health data is captured in systems at the point of care. However, the data and the methods of exchange across systems are inconsistent. For example, data such as the pregnancy history, delivery interventions, plan of treatment information, etc. are captured in the postpartum summary note. Providing the ability to share the postpartum summary note from the delivery setting to the next level of care for use during postpartum care, will assist in assuring that the mother receives safe and effective postpartum care.

Data Class: Clinical Notes
Data Element: Maternal Social Determinants of Health
Comment: The Regenstrief Institute recommends the inclusion of "Maternal Social Determinants of Health". According to a recent report from the U.S. Centers of Disease Control and Prevention (CDC) [2], the maternal mortality rate increased significantly in 2020 (from 20.1 deaths per 100,000 live births in 2019 to 23.8 in 2020). Women of color in the US,

regardless of economic or educational status, are three to five times more likely to die from pregnancy-related causes than white women.

One potential mediator of the disparities observed in U3 populations is social determinants of health (SDOH), including: (i) individual socioeconomic factors; (ii) community factors such as crime, poverty, housing, and the racial/ethnic makeup of the community; and (iii) the physical environment. Factors such as access to education and emergency/health services and stressors such as interpersonal racism, poverty, unemployment, residential segregation, and domestic violence may also increase the vulnerability of women from U3 populations to adverse reproductive health outcomes. Moreover, chronic exposure to excessive social/cultural stressors can have a physiologic cost leading to pregnancy complications such as miscarriages, preterm birth, and pre-eclampsia.
https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-023-01963-x

Data Class: Exposure Contact Information

Data Element: Exposure Contact Agent

Comment: The Regenstrief Institute supports the inclusion of the "Exposure Contact Agent" data element. We recommend that a more precise definition of this data element be developed and used.

This data element is used in electronic case reporting (eCR) which provides case reports to state, tribal, local, or territorial (STLT) public health agencies (PHA) for up to 292 reportable diseases and conditions. Submission of reports of persons with these conditions is required by law in every US State and Territory. Public health epidemiologists have identified the data elements necessary to be included in electronic case reports from healthcare organizations and providers.

FHIR defines exposure/contact information as: "This Observation profile represents potential patient exposure and contact information and should be used to record information about the patient's exposure to an agent (exposure source) or to record information about those that the patient could have exposed to an agent (exposure target). Recording of this information could assist/support in contact tracing or other control measures.

The type of exposure/contact is contained in Observation.code (environmental, activity, event, location, person, animal, etc.). This value could come from one of the following value sets: Exposure Setting (COVID-19), Exposure Location or may be selected from another suitable value set (e.g.: Social History Type). If the exposure/contact is an entity (person, animal, location) then it is represented in Observation.focus which is a reference to a Patient, RelatedPerson, Location, Group, etc.. (An animal would be represented by a RelatedPerson that contains the Extension Practitioner Animal Species). This focus contains either: the patient's contact with an entity (person, animal, or substance) or presence at a location where exposure to an agent could have occurred (acquisition exposure) the patient's contact with an entity (person, animal, or substance) or presence at a location where transmission

from the patient could have occurred (transmission exposure)"
https://build.fhir.org/ig/HL7/case-reporting/StructureDefinition-us-ph-exposure-contact-information.html

The following journal article provides proposals for the definition of exposure: Zartarian VG, Ott WR, Duan N. A quantitative definition of exposure and related concepts. J Expo Anal Environ Epidemiol. 1997 Oct-Dec;7(4):411-37.
PMID: 9306230. https://pubmed.ncbi.nlm.nih.gov/9306230/

Data Class: Health Status Assessment
Data Element: Pain Assessment
Comment: The Regenstrief Institute recommends inclusion of the "Pain Assessment" data element. Pain assessment is a multidimensional observational assessment of a patient's experience of pain. Pain measurement tools are instruments designed to measure pain. There are many pain assessment tools for all ages and many conditions. The ability to collect chest pain and share this data across HIEs is critical in for patient outcomes. For example, the use of FHIR to collect chest pain assessment was defined as any chief complaint where the patient presented with explicit chest pain symptoms, or any other symptoms which could be interpreted as precursors or manifestations of a cardiac diagnosis. Other symptoms included shortness of breath, difficulty breathing, syncope, rib pain, dyspnea, tachycardia, arm pain, chest tightness and chest pressure. Since not all patients with a cardiac condition necessarily present with a chief complaint of chest pain, this broad list enabled the healthcare organization to capture an expanded set of conditions for to provide useful information on their dashboard.

Data Class: Nutrition and Diet
Data Element: Multiple
Comment: The Regenstrief Institute recommends the inclusion of the following data elements within the Nutrition and Diet data class: • Oral Diet Type • Oral Diet Fluid Consistency • Oral Diet Texture Modifiers • Oral Nutritional Supplement • Enteral Nutrition Type • Enteral Nutrition Volume • Enteral Nutrition Rate • Enteral Nutrition Frequency • Enteral Nutrition Additive • Enteral Nutrition Flush

- Eating/Drinking Assistive Device
- Oral Diet Nutrient Modifiers

FHIR Enteral Nutritional resource is present to capture Oral intake of food, fluids, oral nutritional supplements (i.e. Ensure), or enteral nutrition should be recorded using the NutritionIntake resource. Supplements, such as vitamins, minerals, herbals, should be recorded using the medication resources. Parenteral nutrition should be recorded using the medication resources.

The terminologies supporting nutrition and diet are: Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT). LOINC, UCUM.

Data Class: Observations
Data Element: Observation Value
Comment: The Regenstrief Institute supports the inclusion of the "Observation Value" data element. This data element should be collected across all healthcare domains, such as laboratory observables, survey observables, exam findings, assessments, imaging studies, nutritional studies, social history, signs and symptoms, chief complaints, observation value units coming from UCUM, etc. LOINC and UCUM would be the terminology to support the collection of Observation Value" data.