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September 20, 2023

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National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT (ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Dear National Coordinator Tripathi:

Thank you for the opportunity to participate in advancing the US Core Data for Interoperability (USCDI). We recognize the value of USCDI and USCDI+ in advancing clinical data interoperability, standards, and definitions in addressing our challenges with data capture, extraction, analytics, reuse, and workflow. We encourage ONC to push HIT developers and vendors to implement USCDI and its extensions to improve data standardization that supports data extraction, public health reporting and research that informs legislation and regulation.

This document describes in its sections and appendices NACHC's feedback and reiteration of support for the following topics and data elements in both USCDI+ and USCDIv5 moving forward:

1. Reduction of Ambiguity of Definitions for Data Elements
2. Patient Demographics - Sexual Orientation & Gender Identity (SOGI)
3. Patient Demographics - Date of Death
4. Patient Demographics - Tribal Affiliation
5. Patient Demographics – Occupation
6. Patient Demographics – Occupation Industry
7. Health Insurance Information
8. Health Status – Functional Status
9. Health Status – Disability Status
10. Health Status – Mental Function / Mental Health Status and Cognitive Status
11. Health Status – Women's Health - Pregnancy Status / Pregnancy Episode and others
12. Vital Signs - Average Blood Pressure

13. Vital Signs - Date/Time
14. Laboratory – Specimen Type
15. Laboratory – Result Status
16. Social Determinants of Health (SDoH) Data Class and Domains
17. Social Determinants of Health (SDoH) Assessments
18. Social Determinants of Health (SDoH) Goals
19. Social Determinants of Health (SDoH) Problems / Health Concerns
20. Social Determinants of Health (SDoH) Interventions

The **National Association of Community Health Centers (NACHC)** has for more than five decades been a leader in providing high-quality, culturally competent health and wellness care for the nation's most vulnerable people with the least access to care serving 29 million patients annually through 12,000 sites. NACHC's member health centers (Federally Qualified Health Centers (FQHCs) and look-alikes) and partner organizations Primary Care Association (PCA) and Health Center-Controlled Networks (HCCN) are the largest national primary care network providing high quality culturally responsible care to the nations underserved.

Health centers have led the nation in the adoption of electronic health records with support from their partners at NACHC, PCAs, and HCCNs. To meet the needs of community health center patients, we must have electronic clinical resources with low- to no-implementation cost and effort to scale and spread regarding both content and adoption to provide patient/provider centric evidence-based care. The patients of community health centers are often our nation's most vulnerable, with no or limited access to outpatient care and significant social, geographic and health challenges.

Structured data elements and capture for specific data elements accepted in prior USCDI versions such as SDoH and SOGI can inform care delivery, thereby addressing health disparities and empowering providers in achieving health equity. However, if they are not implemented consistently, the amount to which data reuse and exchange occurs in point of care systems is significantly limited.

Health IT has, in the past, exacerbated health inequities because disadvantaged communities lack access to digital devices and broadband and often have language barriers and lower digital health literacy; however, we believe it could be used instead as an opportunity to bridge health disparities by proactively enabling the health care community to coordinate care and integrate value-based, patient-centered care into the EHR workflow more effectively.

NACHC itself hosts a secure cloud data warehouse with support for FHIR and the OMOP data model. NACHC also has created a community health center master data dictionary which aligns and harmonizes data classes, data elements, and comments on these topics from medical specialty associations (e.g., AMA, ACOG), standards development organizations (e.g., HL7) academia and health center partner organizations to define consistently clinical and social concepts for use in community health centers.

Reduction of Ambiguity of Definitions for Data Elements

NACHC encourages ONC to address issues with ambiguities and optionality in current USCDI structures and definitions, particularly in relation to the next versions of the HL7 FHIR (Fast Healthcare Interoperability Resources) US Core and HL7 CDA C-CDA Companion Guides. These ambiguities pose challenges in updating implementation guides to meet ONC's certification test requirements and to be considered conformant to USCDI specifications. NACHC encourages ONC to push the definition of data elements to be defined by specific data element codes, to add formal definitions of concepts and data classes for all USCDI members, required support for metadata elements needed to validate and interpret clinical and other data, and named and coded value sets wherever possible for grouped concepts and metadata.

Data element definitions referencing submissions that may contain more information than implied or related to the concept are examples of ambiguity that affects the semantic precision of the concepts. Additionally, there is uncertainty regarding the interpretation of certain terms, like "medication administration" and "laboratory tests," and the inclusion of "reason for referral" under the "Procedure" data class. Furthermore, issues arise with concepts like "Care Experience Preferences" and "Clinical Notes," where it's unclear whether they refer to patient-expressed preferences or provider-understood preferences. There's also a lack of clarity regarding the representation of LOINC codes for clinical notes. For example, guidance naming multiple code systems could be improved by naming one as the primary code system and providing guidance on using alternatives in translation and how to approach when an appropriate code does not exist.

These ambiguities could be addressed through a more rigorous modeling approach, either by closely following HL7 V3 RIM (Reference Information Model) or adopting an HL7 FHIR approach with more tightly scoped concepts. These approaches emphasize the need for clear, complete definitions mapped to the intended scope and standard codes for optimal USCDI conformance.

NACHC recommends that USCDI resources provide greater granularity and clarity, specifying the intended resources in scope and clearly defining the binding to key vocabulary. This would serve as a solid foundation for any use of USCDI and allow for more accurate and predictable production of interoperability specifications by HL7 and other organizations.

Patient Demographics - Sexual Orientation & Gender Identity

Collecting SO/GI data is essential to providing high-quality, patient-centered care for transgender people. ONC has provided good leadership on the standardization of this content in USCDIv2. FQHCs are required to collect these data for all their patients and report them to HRSA so these data are well established and are imperative to the patient-centered provision of care.

SO/GI data can be collected in several ways:

> 1. Information can be obtained through patient portals and transmitted to an individual's EHR. This approach is attractive because it puts the patient in charge of defining their own identity and needs.
> 2. Questions can be included on registration forms for all patients as part of the demographic section along with information about race, ethnicity, and date of birth.
> 3. Providers and their care team can ask questions during the patient visit, for instance, as part of a social or sexual history discussion.

To address the lack of SO/GI data in health systems, the Department of Health and Human Services' (HHS's) Healthy People 2020 included an objective to "increase the number of states, territories, and the District of Columbia that include questions that identify sexual orientation and gender identity on state level surveys or data systems" to improve "the health, safety, and well-being of lesbian, gay, bisexual, and transgender (LGBT) individuals." Increasing the number of population-based data systems that collect standardized data on (or for) lesbian, gay and bisexual populations and on (or for) transgender populations and expanding the availability of sexual orientation/gender identity (SO/GI) statistics have also been priorities for other federal agencies.

Sexual Orientation

NACHC believes sexual orientation is a core component of many patients' identities. However, it is also associated with serious health inequity and health disparities. Furthermore, it is clinically relevant to several domains of sexual health, trauma and interpersonal violence, substance abuse and mental health risk factors. Michigan students identifying as lesbian, gay, or bisexual reported higher rates than their peers for measures of bullying, missing school due to fear for their safety, and were more than three times as likely to report seriously considering suicide in the past year.

We strongly support the requirement for sexual orientation data to be captured in a standardized way in EHRs to support patients' identities, reduce health disparities and facilitate effective clinical risk that may be modified by sexual orientation.

Gender Identity

NACHC believes gender identity is a foundational component of patient identity. However, it is also associated with serious health inequity and health disparities. Furthermore, it is clinically relevant to several domains of sexual health, cancer risk, trauma and interpersonal violence, substance abuse and mental health risk factors.

We strongly support the requirement for gender identity data to be captured in a standardized way in EHRs to support patients' identities, reduce health disparities and facilitate effective clinical risk that may be modified by sexual orientation. However, NACHC proposes the following harmonization to the gender identity value sets on SNOMED-CT and LOINC based on work from the Gender Identity Working Group at HL7:
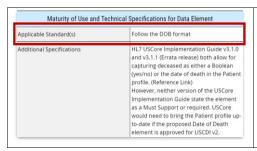
Commented [JS1]: Missing value set or link

Commented [RUN2R1]: resolved

1. ~~Gender Identity~~ Gender Identity
   a. https://confluence.hl7.org/display/VOC/Gender+Identity
      i. SNOMED-CT
         1. Male.
            a. 446151000124109
         2. Female.
            a. 446141000124107
         3. Female-to-Male (FTM)/Transgender Male/Trans Man.
            a. 407377005
         4. Male-to-Female (MTF)/Transgender Female/Trans Woman.
            a. 407376001
         5. Genderqueer, neither exclusively male nor female.
            a. 446131000124102
         6. Additional gender category or other, please specify.
            a. nullFlavor OTH
         7. Choose not to disclose.
            a. nullFlavor ASKU
      ii. LOINC
         1. Concept   76691-5
         2. Answer List   LL3322-6
            a. Identifies as male.
               i. LA22878-5
            b. Identifies as female
               i. LA22879-3
            c. Female-to-male transsexual
               i. LA22880-1
            d. Male-to-female transsexual
               i. LA22881-9
            e. Identifies as non-conforming
               i. LA22882-7
            f. Other
               i. LA46-8
            g. Asked but unknown
               i. LA20384-6
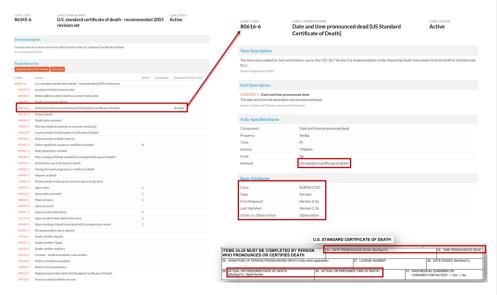
Patient Demographics - Date of Death

NACHC is supportive of a standards-based concept of date and time of death; however, we feel more guidance and support would be useful to accompany this concept. The accepted data element submission page does not point to a specific concept for date of death.

Maturity of Use and Technical Specifications for Data Element	
Applicable Standard(s)	Follow the DOB format
Additional Specifications	HL7 USCore Implementation Guide v3.1.0 and v3.1.1 (Errata release) both allow for capturing deceased as either a Boolean (yes/no) or the date of death in the Patient profile. (Reference Link) However, neither version of the USCore Implementation Guide state the element as a Must Support or required. USCore would need to bring the Patient profile up-to-date if the proposed Date of Death element is approved for USCDI v2.

The applicable standard specified in the draft USCDIv3 submission does not identify a terminology standard but specifies a data format.
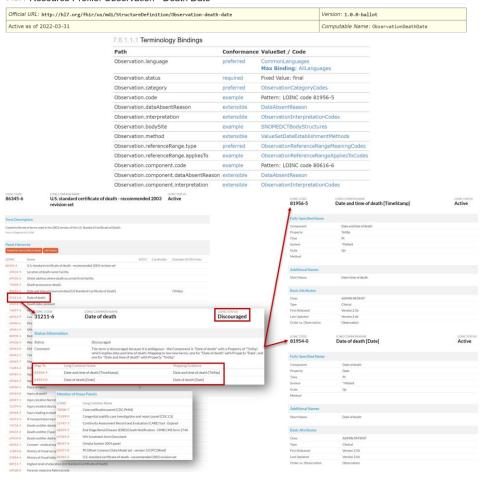
We recommend modifications in this field to specify adherence to a clinical terminology standard such as LOINC and SNOMET-CT to represent the concept of Date of Death.

NACHC suggests the use of the LOINC code 80616-6 as the appropriate term due to its use in federal programs for death reporting and certification.
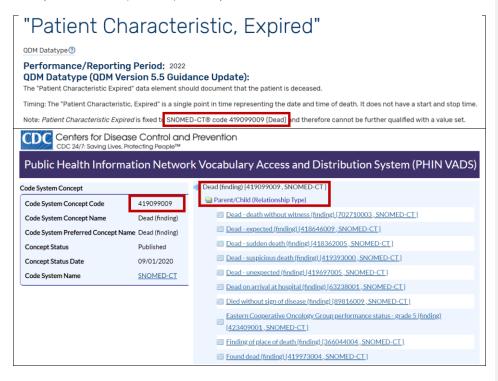
NACHC is sensitive to the fact that in some use cases a date of death may be available but not a time, and so suggests that the implementation guidance in this case addresses the situation in which date but not time are available by defaulting to a null time or by linking this code to the clinical date of death code 81954-0 which specifies a date and not a date/time and could be mapped to an 80616-6 code with a null time.

7.6.1 Resource Profile: Observation - Death Date

Official URL: http://hl7.org/fhir/us/mdi/StructureDefinition/Observation-death-date	Version: 1.0.0-ballot
Active as of 2022-03-31	Computable Name: ObservationDeathDate

7.6.1.1.1 Terminology Bindings

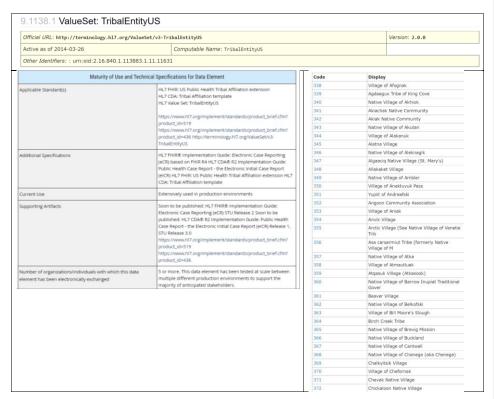| Path	Conformance	ValueSet / Code
Observation.language	preferred	CommonLanguages **Max Binding:** AllLanguages
Observation.status	required	Fixed Value: final
Observation.category	preferred	ObservationCategoryCodes
Observation.code	example	Pattern: LOINC code 81956-5
Observation.dataAbsentReason	extensible	DataAbsentReason
Observation.interpretation	extensible	ObservationInterpretationCodes
Observation.bodySite	example	SNOMEDCTBodyStructures
Observation.method	extensible	ValueSetDateEstablishmentMethods
Observation.referenceRange.type	preferred	ObservationReferenceRangeMeaningCodes
Observation.referenceRange.appliesTo	example	ObservationReferenceRangeAppliesToCodes
Observation.component.code	example	Pattern: LOINC code 80616-6
Observation.component.dataAbsentReason	extensible	DataAbsentReason
Observation.component.interpretation	extensible	ObservationInterpretationCodes

It should be noted that the FHIR profile referenced in comment for DeathCertification, for example, references SNOMED-CT concepts (SCT 419099009) and not LOINC and it is expected that the USCore profile would reference the LOINC code for both patient deceased and date of death (LOINC 80816-6, 81956-5, 81954-0).
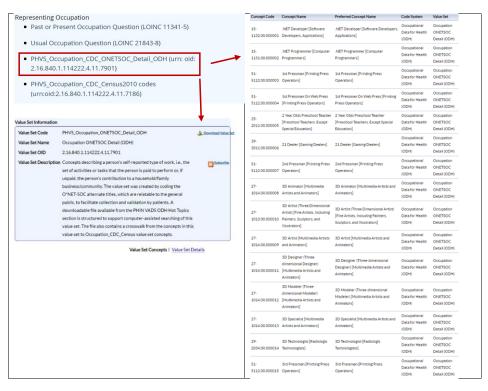
Patient Demographics - Tribal Affiliation

9.1138.1 ValueSet: TribalEntityUS

Official URL: **http://terminology.hl7.org/ValueSet/v3-TribalEntityUS**	*Version*: **2.0.0**
Active as of 2014-03-26	*Computable Name*: **TribalEntityUS**
Other Identifiers: : urn:oid:2.16.840.1.113883.1.11.11631	

Maturity of Use and Technical Specifications for Data Element	
Applicable Standard(s)	HL7 FHIR: US Public Health Tribal Affiliation extension HL7 CDA: Tribal Affiliation template HL7 Value Set: TribalEntityUS https://www.hl7.org/implement/standards/product_brief.cfm?product_id=519 https://www.hl7.org/implement/standards/product_brief.cfm?product_id=436 http://terminology.hl7.org/ValueSet/v3-TribalEntityUS
Additional Specifications	HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) based on FHIR R4 HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) HL7 FHIR: US Public Health Tribal Affiliation extension HL7 CDA: Tribal Affiliation template
Current Use	Extensively used in production environments
Supporting Artifacts	Soon to be published: HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) STU Release 2 Soon to be published: HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 1, STU Release 3.0 https://www.hl7.org/implement/standards/product_brief.cfm?product_id=519 https://www.hl7.org/implement/standards/product_brief.cfm?product_id=436
Number of organizations/individuals with which this data element has been electronically exchanged	5 or more. This data element has been tested at scale between multiple different production environments to support the majority of anticipated stakeholders.

Code	Display
338	Village of Afognak
339	Agdaagux Tribe of King Cove
340	Native Village of Akhiok
341	Akiachak Native Community
342	Akiak Native Community
343	Native Village of Akutan
344	Village of Alakanuk
345	Alatna Village
346	Native Village of Aleknagik
347	Algaaciq Native Village (St. Mary's)
348	Allakaket Village
349	Native Village of Ambler
350	Village of Anaktuvuk Pass
351	Yupiit of Andreafski
352	Angoon Community Association
353	Village of Aniak
354	Anvik Village
355	Arctic Village (See Native Village of Venetie Trib
356	Asa carsarmiut Tribe (formerly Native Village of M
357	Native Village of Atka
358	Village of Atmautluak
359	Atqasuk Village (Atkasook)
360	Native Village of Barrow Inupiat Traditional Gover
361	Beaver Village
362	Native Village of Belkofski
363	Village of Bill Moore's Slough
364	Birch Creek Tribe
365	Native Village of Brevig Mission
366	Native Village of Buckland
367	Native Village of Cantwell
368	Native Village of Chenega (aka Chenega)
369	Chalkyitsik Village
370	Village of Chefornak
371	Chevak Native Village
372	Chickaloon Native Village

NACHC believes tribal affiliation is a foundational component of patient identity and required for patient-centered care. We strongly support the use of the code systems and codes described by the Tribal Entity code systems to ensure robust and patient-centered support for patients with tribal affiliation in the US healthcare system.

Patient Demographics – Occupation and Industry

NACHC believes occupational health is central to understanding patient risk and context in a patient-centered way. We firmly support the use of the code systems and codes described by CDC-NIOSH and we can further state we are working with 3 clinical organizations using 3 different EHRs to implement these codes in production at this time.

NACHC believes occupational health is central to understanding patient risk and context in a patient-centered way. We firmly support the use of the code systems and codes described by CDC-NIOSH and we can further state we are working with 3 clinical organizations using 3 different EHRs to implement these codes in production at this time.

Health Insurance Information

NACHC believes health insurance information is critical to support patient access and care systems that support appropriate prescribing, referral, and benefits delivery. We strongly support the use of the code systems and codes described by the code systems to ensure robust and patient-centered support for patients in the US healthcare system.

Health Status – Functional Status

NACHC is supportive of the concept of functional status; however, it is not likely to support interoperability to solely create a terminology binding to support the concept. Because concepts in the draft version are in fact different types of functional status or causes of disability, we believe that creating a class for this concept will likely create larger transitions of care documents without being able to be processed by receiving systems. This approach creates liability for providers who at best can use this data as free text in this case and contributes to data overload and burnout. We strongly recommend providing either specific category of functional status with equivalent semantics and clear terminology bindings.

Health Status – Disability Status

NACHC is supportive of the concept of disability status; however, it is not likely to support interoperability to solely create a terminology binding to support the concept. Because the concepts in the draft version generally represent non-semantically equivalent types of disability status and observations about these conditions, we believe that creating a class for this concept will likely create larger transitions of care documents without being able to be processed by receiving systems. This approach creates liability for providers who at best can use this data as free text in this case and contributes to data overload and burnout. We strongly recommend providing either specific category of functional status with equivalent semantics and clear terminology bindings.

Health Status – Mental Function / Mental Health Status and Cognitive Status

NACHC supports the separation of the current "Mental/Cognitive Status" element into two distinct components: "Mental Health Status" and "Cognitive Status". While these elements naturally fall under the broader category of "Health Status Assessment", it is crucial to recognize their unique clinical nature and definitions. "Cognitive Status" is assessed using established measures like MoCA, SLUMS, or MMSE, evaluating orientation, attention, memory, judgment, and reasoning. In contrast, "Mental Health Status" encompasses diagnoses such as depression, anxiety, and ADHD, and is evaluated using validated assessments like PHQ-9, GAD-7, and the Vanderbilt Assessment Scale.

The urgency of this matter is underscored by staggering statistics from the Centers for Disease Control and Prevention (CDC). Over 50% of individuals in the United States will receive a mental health diagnosis in their lifetime, with more than 57 million annual visits to physician offices where mental disorders are the primary diagnosis. Additionally, the U.S. Preventive Services Task Force (USPSTF) has recommended depression screening for various populations since 2016, extending to adolescents, children, and pregnant or postpartum women as of 2022.

Furthermore, the National Committee for Quality Assurance (NCQA) places a high priority on the diagnosis of depression due to its well-documented impact on physical health, mental health, and functional status. This commitment led to the development of five depression care measures within the Healthcare Effectiveness Data and Information Set (HEDIS), notably focusing on the PHQ-9 assessment tool.

We believe that implementing these recommendations will significantly enhance the comprehensive assessment of mental health, leading to more effective care and improved patient outcomes.

Health Status – Pregnancy Status | Women's Health

Maternal morbidity and mortality remain significant public health concerns in the United States, particularly among medically underserved and uninsured populations that community health centers serve. Standardizing critical pregnancy-related data in electronic health records (EHRs) is crucial for informing care decisions, coordinating maternal care, and improving care quality.

The CDC's Division of Reproductive Health, in collaboration with the National Association of Community Health Centers (NACHC), has made substantial progress in enhancing the quality of pregnancy and postpartum care within Federally Qualified Health Centers (FQHCs). By leveraging Health Information Technology (HIT) systems, they have successfully tracked and analyzed pregnancies, identified high-risk cases, and improved data standardization in EHRs. The initiative has revealed significant gaps in maternal care quality in community health centers.

The inclusion of standardized data elements like Pregnancy Status, Estimated Date of Delivery, and Pregnancy Outcome in the U.S. Core Data for Interoperability (USCDI) is crucial for improving maternal healthcare, research, and quality measurement. This is especially important for conditions like hypertensive disorders of pregnancy, which disproportionately affect certain demographics, including Black and Native American/American Indian individuals.

Pregnancy Status was previously proposed and submitted by NACHC in coordination with ACOG for consideration in both USCDIv1 and USCDIv2. While NACHC agrees that there is a critical need for the pregnancy status data element, the currently submitted concept profile should not ideally be referenced from IPS as the submission is not harmonized with electronic case reporting (eCR) LOINC code for pregnancy status (LOINC 82810-3) with its terminology bound answer codes (LOINC LL4129-4), and with SNOMED-CT terminology bindings. This code is referenced in the federally supported Family Planning Annual Report (FPAR) program and data system from HHS, which we believe should be included as a reference in version 5 draft. The currently accepted IPS "Pregnancy Status" submission standards specifications is missing the recommended 82810-3 LOINC code.

NACHC is supportive of ACOG's position supporting HL7's CCDA "Pregnancy Status" and related women's health data elements as its own data class listed in Appendix C. NACHC also supports the formal definitions and additional women's health data elements in the following table:

Data element	Definition	Use case
Pregnancy status	Indicator that patient is currently pregnant, not pregnant, or that their pregnancy status is unknown currently	Identify pregnancy episodes to help health care providers make informed decisions for the care of the patient and to inform quality improvement initiatives to improve the follow-up and documentation of peri- and postpartum care services. This data element is captured and used by providers using electronic health records or self- reported by patient as patient generated health data. However, this data is not standardized, and data exchange is not interoperable across many settings. Capturing the data related

		to pregnancy status in a standardized way will support the collection of sufficient pregnancy information to identify cases and measure the burden and outcomes of pregnancy on a population level.
Estimated Date of Delivery (Submitted 3/2022)	Date representing the expected delivery date of a pregnancy	Estimate accurate pregnancy start date to provide pregnancy information and provide key birth statistics that identify public health trends. This data element is critical for supporting maternal care coordination and care provisions. The use case will be relevant for all maternal health patients, all providers involved in maternal health care, and all consumers of maternal health data used for research, public health and patient care and quality outcomes.
Estimated Gestational Age	The gestational age (in weeks, or weeks and fraction of week) of the pregnancy at time of pregnancy outcome	Estimate due date to inform obstetrical care and testing and evaluate the fetal growth and infant's health at birth. The use case will be relevant for all maternal health patients and infants, all providers involved in maternal and infant health care, and all consumers of maternal and newborn health data used for research, public health and patient care and quality outcomes.
Pregnancy outcome (Submitted 3/2022)	The outcome of the pregnancy: live birth; 2) still birth or intrauterine fetal death (>20 weeks gestation); 3) miscarriage/spontaneous abortion (<20 weeks gestation); 4) termination (elective, medical, surgical, or induced abortion); 5) ectopic pregnancy; 6) non-live birth, not otherwise specified	Document pregnancy outcomes to assess care processes and develop effective approaches to maternal care. Linkages between mother and infant records will also be beneficial for clinical care as well as for public health (important to link data on mothers and infants especially for diseases such as Zika, Hep B, and others). This data is also routinely exchanged for birth certification, fetal death reporting, and birth defect reporting. Standardization will benefit the data exchange between EHR systems and public health, specialized registries, national health care survey systems, and research entities.

Date of pregnancy outcome (Submitted 3/2022)	Date when an event occurred relative to pregnancy outcome	Document date of when the pregnancy outcome occurred. The use case will be relevant for all maternal health patients, all providers involved in maternal health care, and all consumers of maternal health data used for research, public health and patient care and quality outcomes.
Pregnancy complications	Complications of pregnancy that include physical and mental conditions that affect the health of the pregnant or postpartum person, the infant, or both.	Identify adverse pregnancy complications that can have lifelong effects on the pregnant individual's health, such as developing hypertension or cardiovascular disease post-delivery, as well the infant's health. The use case will be relevant for all maternal health patients, all providers involved in maternal health care, and all consumers of maternal health data used for research, public health and patient care and quality outcomes.
Postpartum status	The time period after delivery up to 12-months	Identify time period subsequent to pregnancy episode and patients who should receive specific postpartum care services. The use case will be relevant for all maternal health patients, all providers involved in maternal health care, and all consumers of maternal health data used for research, public health and patient care and quality outcomes.
Postpartum care visit	Postpartum care visit (occurring within 3-12 weeks after delivery)	Increase the proportion of all postpartum patients who receive initial postpartum care from -their obstetrician–gynecologists or primary care providers based on current or existing guidance and recommendations. Underutilization of postpartum care impedes management of chronic conditions, such as mental health, diabetes, hypertension, and obesity, and access to effective contraction, which increases the risk of short interval pregnancy and preterm birth. The use case will be relevant for all maternal health patients, all providers involved in maternal health care, and all consumers of maternal health data used for

		research, public health and patient care and quality outcomes.
Postpartum care visit quality services	Provide evidence-based quality postpartum care services at visit: 1) contraceptive counseling and provision of a contraceptive method (LOINC 86654-1); 2) postpartum depression screening within 8 weeks of delivery (LOINC 89211-7); 3) postpartum depression treatment for those diagnosed with postpartum depression (LOINC 71354-5); 4) postpartum diabetes screening for women with GDM-affected pregnancy; 5) pregnancies with chronic or gestational hypertension (ICD 10 O13.9; 6) pregnancies with hypertension in pregnancy and subsequent preeclampsia (ICD 10 O14.95), eclampsia (ICD 10 O14.90) and HELLP syndrome (ICD-10 code O14.24) outcomes; 7) breastfeeding (LOINC 63895-7); 8) infant feeding and care; and 9) other evidence-based recommendations for postpartum care services	Track postpartum care service provision to reduce gaps in care and improve adherence to evidence-based guidelines. The use case will be relevant for all maternal health patients and infants, all providers involved in maternal health care, and all consumers of maternal health data used for research, public health and patient care and quality outcomes.

Vital Signs - Average Blood Pressure

We applaud the inclusion of Average Blood Pressure on USCDIv4, but Vital Signs – Date and Time is a crucial metadata that is currently not included in USCDIv5 draft.

Vital Signs – Date and Time

NACHC supports promoting 'Vital sign results: date and timestamps' from Level 2 to draft USCDI v5. While we acknowledge that Average Blood Pressure is crucial in assessing health risks, its interpretation requires details like time, readings, and protocols. In July 2023, ONC acknowledged this need for additional information on average blood pressure. The '*Vital sign results: date and timestamps*' element can supply this information. Different measurement protocols also yield varying hypertension thresholds, emphasizing the need for accurate protocol knowledge in tandem with vital signs metadata. Various clinical scenarios need accurate time and date stamps in proper ISO 8601 format, such as consecutive days for home vital signs measurements, single dates for clinic readings, and specific timeframes for ambulatory measurements. NACHC urges ONC to include this element in draft USCDI v5 for better contextualizing average blood pressure.

Date and time is supported by HL7 DTM, defining the following format:

YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]]][+/-ZZZZ].

The time zone (+/-ZZZZ) is represented as +/-HHMM offset from Coordinated Universal Time (UTC) (formerly Greenwich Mean Time (GMT)), where +0000 or -0000 both represent UTC (without offset). The specific data representations used in the HL7 encoding rules are compatible with ISO 8824-1987(E).

Laboratory – Specimen Type

Specimen type is a critical component to understanding and validating laboratory tests and results for both clinical care and public health. However, the submission here points to a website that discusses the electronic laboratory reporting program and not to a standard. The link to PHINVADS here similarly does not reference any specific value sets. NACHC believes this data element should reference one or more value sets (with or without relevant standards/profiles) that consist of implemented and validated concepts used in the existing laboratory standards.

Laboratory – Result Status

Result is a critical component to understanding and validating laboratory tests and results for both clinical care and public health. However, the submission here points to multiple standards relevant to electronic laboratory reporting. NACHC believes the submission here should first reference lab interoperability use cases for point of care delivery. This data element should first and foremost reference one or more value sets that consist of implemented and validated concepts used in the existing laboratory standards and then the appropriate HIT standards that use it.

Possible Relevant Value Sets:
HL7 v2 approach:
Result status
https://hl7-definition.caristix.com/v2/HL7v2.3/Tables/0123

Observation Result Status
https://hl7-definition.caristix.com/v2/HL7v2.3/Tables/0085

Possible Relevant Value Sets:
FHIR approach:
Diagnostic Report Status
https://build.fhir.org/valueset-diagnostic-report-status.html
Observation Status
https://fhir-ru.github.io/valueset-observation-status.html

While USCDI does provide a de facto data model and reference some existing standards in the point of care and laboratory reporting use cases, a coherent approach that takes the lab data from the manufacturer through point of care testing to electronic reporting is in development to pull all the relevant components of all the related use cases together in a project called SHIELD (Systemic Harmonization and Interoperability Enhancement of Laboratory Data). A long term approach that aligns all the use cases is optimal.

https://mdic.org/program/systemic-harmonization-and-interoperability-enhancement-for-lab-data-shield/

Social Determinants of Health (SDoH) Problems / Health Concerns - Data Class and Domains

Social Determinants of Health have been defined as:
"...the conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks." (https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health).

They are a primary source of health inequities, lead to poorer health outcomes and interfere with a patient's ability to participate in a health treatment plan. FQHCs have always been leaders in responding to SDOH concerns, as they serve populations with a high burden of unmet social and financial needs, and by definition provide enabling services, including case management, referrals, translation/interpretation, transportation, eligibility assistance, health education, environmental health risk reduction, health literacy, and outreach. These health-related and non-medical services address unmet needs that would interfere with successful participation in a medical treatment plan. Furthermore, health centers respond in a culturally-competent way, with diverse staff, community outreach and mental health and other emotional support tools.

NACHC is the co-creator and co-owner of PRAPARE, a national standardized patient risk assessment protocol built into the EHR designed to engage patients in assessing and addressing social determinants of health.

Figure 1 Core and optional set of SDOH collected through PRAPARE

While FQHCs have been successful in asking their patients about and responding to SDOH needs, they have struggled to integrate these data into their EHRs and workflows in part because of lack of standardization around the data form and manner and the lack of regular use of structured terminology to describe these data (see Figure 2 below). Standardizing the PRAPARE domains and coding along with the Uniform Data Set (UDS) domains would significantly improve this gap. Further work is needed to fill in similar gaps around essential services and social interventions and we encourage ONC to create a data class for Social Interventions which we would suggest would be used both for Referrals and for Encounters for social services.

Figure 2 Distribution of EHR use-purpose in FQHCs (Left), distribution of SDOH collection tools (right)

Addressing SDOH in clinical settings:

To address SDOH in clinical settings we will need to promote content to facilitate improved patient-centered outcomes. To that extent, NACHC has initiated a working collaboration with EHR vendors and Community Health Center partners to improve the collection and operationalization of SDOH data. Our model, highlighted in Figure 3, includes an expansion of the team curating the problem list, coupled with a share care plan between various health care providers. To this extent, we support electronic care plan standards for documentation and interoperability.

Figure 3 Theoretical framework for addressing ad caring for SDOH data in EHRs via eCare Planning

Social Determinants of Health (SDoH) Assessments

NACHC firmly believes that the collection of social determinants of health information is critical to support patient access and referral care systems that enable and optimize appropriate closed-loop social interventions.

We strongly support the use of the code systems and codes referenced by the Gravity Project submission to ensure proper representation of PRAPARE and other SDoH assessment screening tools to support interoperability of this data to connect CBOs and CCOs to EHRs.

Social Determinants of Health (SDoH) Goals & Interventions

NACHC is strongly supportive of the use of both the Goals and Interventions concepts already present in UCSDIv2 although does not agree with the proposal to break up goals into multiple data elements based on the domain of the care plan.

The intent of the Care Plan DAM is to normalize problem list items with other health concerns and social needs on a relatively equal footing and to refocus the care plans around the patient's stated goals. The effect of creating a separate concept for SDOH goals undoes the intent of Goals as described by the DAM. While it seems that coded elements would improve interoperability, in fact coded goals in the sense of social services and health concerns reduces the patient-centered nature of the Goals concept and instead encourages care team members to document a generic "goal" which is not the one stated by the patient but instead the closest coded concept.

The use of coded terms should not be prohibited, but the emphasis of the goals field should be on the patient's stated goals in addition to those which might be added by care team members (e.g. increased ROM to 90* or Hba1c <7)

Ongoing Challenges in FQHCs to Data Exchange using Federal Interoperability Standards

In the past decade, adoption of certified EHRs has gone from limited to nearly universal and community health center EHR use is like that of other ambulatory settings. However, despite the use of these certified HIT systems, there are significant gaps in our ability to effectively capture and extract critical health and administrative data. We think that ONC may not be aware that even where there is required support for elements in the USCDI, local customers are not able to access the data according to those standards. For example, we have encountered customers of multiple vendors who are not able to use RxNorm codes to describe or find their medication data. This means that at the site or center level there are staff who are manually entering drug names and using these to code the data at the patient level. This results in duplicate entries, laborious and difficult data extraction efforts and the potential for adverse events. We encourage ONC to advance their certification testing to production systems to clarify the system functionality that should be made available across the vendor systems to define data using coded terminologies required in USCDI and for shared program requirements and to ensure that these can be used to freely extract data at the site level for quality improvement and reporting. NACHC welcomes an invitation from ONC to demonstrate how these gaps are harming efforts to improve public health and patient care.

NACHC believes that the USCDI has the potential to create the kind of semantic interoperability the industry still needs to enable seamless data exchange and plug and play interoperability.

Thank you for your support for this critical mechanism to support interoperability, the learning health system, and the effective delivery of care in community health using HIT.

If you have any questions, please contact Julia Skapik at jskapik@nachc.com for any follow up information.

Sincerely,

Julia Skapik, MD, MPH, FAMIA
Chief Medical Informatics Officer
National Association of Community Health Centers

Appendix A: Social Determinants of Health

PRAPARE

PRAPARE is a national standardized patient risk assessment protocol built into the EHR designed to engage patients in assessing and addressing social determinants of health, and it is endorsed by NACHC.
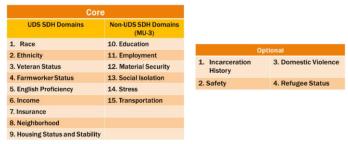

Figure 1 Core and optional set of SDOH collected through PRAPARE

PRAPARE Elements included in ISA

1. Food Insecurity	
Requirement Level	Must Have
Value set	LOINC® 88121-9 Hunger Vital Sign [HVS] LOINC® 88122-7 Within the past 12 months we worried whether our food would run out before we got money to buy more [U.S. FSS] LOINC® 88123-5 Within the past 12 months the food we bought just didn't last and we didn't have money to get more [U.S. FSS] LOINC® 88124-3 Food insecurity risk [HVS] LOINC® 93025-5 Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel In the past year, have you or any family members you live with been unable to get any of the following when it was really needed? Check all that apply. ☐ Food ☐ Clothing ☐ Utilities ☐ Childcare ☐ Medicine or any health care (medical, dental, mental health, vision) ☐ Phone ☐ Other please write: ☐ I choose not to answer this question Z59.4 Lack of adequate food and safe drinking water Z72.4 Inappropriate diet and eating habits Z91.120 Patient's intentional under dosing of medication regimen due to financial hardship Z59.5 Extreme Poverty (100% FPL or below) • Z59.6 Low income (200% FPL or below)
Comments	12% of American families are considered food insecure, the COVID pandemic has exposed many more to this issue.
Use Case	The Use Case for food insecurity is to make sure patients have enough nutrition to achieve their best clinical outcomes. This is important for diabetes and other chronic disease care as well as for both research and public health use cases.
Related Materials	https://www.healthit.gov/isa/representing-food-insecurity https://www.nachc.org/research-and-data/prapare/

2. Housing Insecurity

Requirement Level	Must Have
Value set	What is your current housing situation? (LOINC® code 71802-3) Answer list (LOINC® code LL5350-5) 1. I have housing 2. I do not have housing (staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, or in a park) 3. I choose not to answer that question Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel (LOINC® code 93025-5) Are you worried about losing your housing [PRAPARE] (LOINC® code 93033-9) Z59 Problems related to housing and economic circumstances Z59.0 Homelessness Z59.1 Inadequate housing Z59.2 Discord with neighbors, lodgers, and/or landlord Z59.5 Extreme poverty (100% FPL or below) Z59.6 Low income (200% FPL or below) Z59.8 Other problems related to housing and economic circumstances
Comments	About 1 in every 17 Americans is homeless, and many more are unstably housed or at risk for eviction
Use Case	The Use Case for housing insecurity is to ensure patients have appropriate shelter, a key element of one's determinants of health. This is important for all aspects of one's care as well as for both research and public health use cases.
Related Materials	https://www.healthit.gov/isa/representing-housing-insecurity https://www.nachc.org/research-and-data/prapare/

3. Transportation Insecurity

Requirement Level	Must Have
Value set	Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living? [PRAPARE] (LOINC® code 93030-5) Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel (LOINC® code 93025-5)
Comments	Transportation Insecurity has a high (5/5) ISA adoption level. Transportation is an important aspect of one's ability to receive care, especially in-person care. This is particularly important for rural communities.
Use Case	The Use Case for ensuring patients have the necessary means to attend medical care. This is important for overall care as well as for both research and public health use cases.
Related Materials	https://www.healthit.gov/isa/representing-transportation-insecurity https://www.nachc.org/research-and-data/prapare/

PRAPARE Elements not included in ISA

1. Veteran Status	
Requirement Level	Must Have
Value set	[PRAPARE] Have you been discharged from the armed forces of the United States? ☐ Yes ☐ No ☐ I choose not to answer this question Z56.82 Military deployment status Z56 Problems related to employment/ unemployment. Z56.0 Unemployment Z59.0 Homelessness Z59.1 Lack of adequate and affordable housing Z65.5 Exposure to disaster, war, and other hostilities Z57 Occupational exposure to risk factors
Comments	Veterans face unique health challenges arising from their military service. While in service, they face deadly occupational hazards, and upon return, face issues with mental health and reintegration, among other issues. As such, veterans are at heightened risk for certain health outcomes, including Post-Traumatic Stress Disorder and joint replacement surgery.
Use Case	The Use Case for providing competent sensitive care to this category of patients. This is important for improving veteran care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

2. Farmworker Status	
Requirement Level	Must Have
Value set	[PRAPARE] At any point in the past 2 years has seasonal or migrant farm work been your or your family's main source of income? ☐ Yes ☐ No ☐ I choose not to answer this question SNOMED-CT 106390009 - Agricultural/animal husbandry worker (occupation) 20220901 - In paid seasonal work
Comments	Migrant, Seasonal, and Agricultural Workers' health is impacted by the convergence of multiple factors, including mobility and temporality of work, occupational hazards and harsh working conditions, cultural and linguistic barriers, and immigration status, among others. Access to affordable and appropriate health care is often rare. As a result, migrant, seasonal, and agricultural workers are at high risk for many clinical, non-clinical, and communal health needs.
Use Case	The Use Case for improvement of health care services to essential workers. This is important for pandemic related care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

3. English Proficiency	
Requirement Level	Must Have
Value set	[PRAPARE] What language are you most comfortable speaking? ☐ English ☐ Language other than English (please write): ☐ I choose not to answer this question

	Z55.0 Illiteracy and low-level literacy Z55.9 Problems related to education and literacy, unspecified. Z60.3 Acculturation difficulty Z60.4 Social exclusion and rejection Z60.5 Target of (perceived) adverse discrimination and persecution
Comments	Over 67 million Americans speak a language other than English at home, and of those 25 million do not speak English "very well". Preventing and reducing adverse events in health care depends on good communication between provider and patient. Research has shown that adverse events that affect limited English-proficient patients are more likely to be caused by communication challenges and are more likely to result in serious harm compared to English-speaking patients. (AHRQ, Improving Patient Safety Systems for Patients with Limited English Proficiency, 2012)
Use Case	The Use Case for providing essential primary and other clinical care to all persons reaching our health care system. This is important for ensuring our health care system can deliver quality and patient-centered care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

4. Income	
Requirement Level	Must Have
Value set	[PRAPARE] In the past year, what was the total combined income for you and the family members you live with? This information will help us determine if you are eligible for any benefits. ☐ Please write: ☐ I choose not to answer this question Z59.5 Extreme poverty (100% FPL or below) Z59.6 Low income (200% FPL or below) Z59.7 Insufficient social insurance and welfare support Z72.4 Inappropriate diet and eating habits
Comments	Income is a well-documented factor related to health outcomes. For example, it is associated with lower life expectancy. Financial resource strain that results from insufficient income has been shown to lead to stress, depressed mood, self-rated poor health, smoking, and other substance abuse behaviors. Income is a significant determinant of health, impacting one's ability not only to receive care but also from accessing the care they need
Use Case	The Use Case for making sure patients means can access care they need. This is important for all aspects of care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

5. Insurance Status	
Requirement Level	Must Have
Value set	[PRAPARE] What is your main insurance? ☐ None/uninsured ☐ Medicaid ☐ CHIP Medicaid ☐ Medicare ☐ Other public insurance (not CHIP) ☐ Other public insurance (CHIP) ☐ Private Insurance Z59.7 Insufficient social insurance and welfare support
Comments	Giving the nature of the American health care system, having insurance is a significant determinant of one's ability to receive care.

	Insurance coverage affects access to care and quality of care. More importantly being underinsured, or not insured at all greatly effects a person's ability to be seen in a clinical care setting and can ultimately be the determining factor in an individual's continuity of care as well as their overall physical and mental health and well-being
Use Case	The Use Case for insurance status is to provide a clear picture of access to care in the US. This is important for all aspects care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

6. Neighborhood (US Zip Code)	
Requirement Level	Must Have
Value set	[PRAPARE] What address do you live at? Street, City, State, Zip code
Comments	Population level data on risks and assets can be used to estimate risk for individuals living within that population, ranging from safety, resources available for healthy living, and economic opportunity. Patient address can be used with geocoded data sets, which have been rapidly growing and will likely expand much further in the next few years. Geocoded information on risk reduces the burden of primary data collection. The zip code where one comes from is often considered a more valuable social determinant of health than any other data point,
Use Case	The Use Case for neighborhood information is to assess patient risk for a variety of social and environmental harm. This is important for case management, social care as well as for both research and other public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

7. Education	
Requirement Level	Must Have
Value set	[PRAPARE] What is the highest level of school that you have finished? ☐ Less than high school degree ☐ High school degree or GED ☐ More than high school degree ☐ I choose not to answer this question Z55.0 Illiteracy and low-level literacy Z55.1 Schooling unavailable or unattainable Z55.2 Failed School Examinations Z55.3 Underachievement in School Z55.4 Educational maladjustment and discord with teachers and classmates Z55.8 Other problems related to education and literacy
Comments	Education is a widely used measure of socio-economic status and is a significant contributor to health and prosperity. Higher education is associated with longer life-span and fewer chronic conditions. Parental education is a determinant of child health outcomes. Education attainment often determines one occupation and ability to have proper housing and employment benefits. All of these can have significant impact on a patient's overall health
Use Case	The Use Case for education is to provide a comprehensive picture of the patient health profile. This is important for primary care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

8. Employment	
Requirement Level	Must Have
Value set	[PRAPARE] What is your current work situation? ☐ Unemployed ☐ Part-time or temporary work ☐ Full-time work ☐ Otherwise unemployed but not seeking work (ex: student, retired, disabled, unpaid primary care giver) Please write: ☐ I choose not to answer this question Z56 Problems related to employment/ unemployment Z56.0 Unemployment Z56.1 Change of job Z56.2 Threat of job loss Z56.3 Stressful work schedule Z56.4 Discord with boss and workmates Z56.5 Uncongenial work environment Z56.6 Other physical and mental strain related to work Z56.9 Unspecified problems related to employment Z57 Occupational exposure to risk factors Z59.5 Extreme poverty (100% FPL or below) Z59.6 Low income (200% FPL or below) **See NIOSH code system and MedMorph submission.

Comments	Employment is important for two reasons. The first, because employment can often determine ability to have health insurance and other health benefits. Secondly, the type of job a person has can determine their risk for a given illness (i.e. Essential worker and COVID-19) A good-paying job makes it easier for workers to live in healthier neighborhoods, provide quality education for their children, secure child care services, and buy more nutritious food— all of which affect health. In addition to a stable income, employers can provide benefits, including health coverage, workplace wellness programs, job safety training, and education initiatives that contribute to workers' quality of life and health. In contrast, unemployment can have multiple health challenges beyond loss of income. The unemployed are more likely to have fair or poor health than continuously employed workers, more likely to develop a stress related condition, and more likely to be diagnosed with depression and report feelings of sadness and worry. (Robert Wood Johnson Foundation, How Does Employment—or Unemployment—Affect Health? 2013)
Use Case	The Use Case for employment is to assess a patient's occupational risk. This is important for occupational, primary and COVID-pandemic-related care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

9. Material Security	
Requirement Level	Must Have
Value set	[PRAPARE] In the past year, have you or any family members you live with been unable to get any of the following when it was really needed? Check all that apply. ☐ Food ☐ Clothing ☐ Utilities ☐ Childcare ☐ Medicine or any health care (medical, dental, mental health, vision) ☐ Phone ☐ Other please write: ☐ I choose not to answer this question Z59.4 Lack of adequate food and safe drinking water Z72.4 Inappropriate diet and eating habits Z91.120 Patient's intentional under dosing of medication regimen due to financial hardship Z59.5 Extreme Poverty (100% FPL or below) Z59.6 Low income (200% FPL or below)
Comments	Material security encompasses both presence of resource and presence of skills and knowledge to manage resources. It is common in households that have material insecurity that patients must make tradeoffs to meet their needs. For example, they may choose not to fill a prescription in order to put food on the table. Overall, material security has been linked to many disparities and has a validated relationship with forgoing care and with cost outcomes Clinical outcomes can be directly to one's material security. For example, if a person may not pay their bills, or other commitments they may not be able to improve clinical outcomes or set priorities for them. A diabetic patient lacking an appropriate kitchen or at-risk for eviction may not be able to focus on improving their A1C levels.

Use Case	The Use Case for material security is to better understand the financial status and resources available to patients. This is important for making sure we have a comprehensive picture of the issues impacting patient care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

10.Social Isolation	
Requirement Level	Must Have
Value set	[PRAPARE] How often do you see or talk to people that you care about and feel close to? (For example: talking to friends on the phone, visiting friends or family, going to church or club meetings) ☐ Less than once a week ☐ 1 or 2 times a week ☐ 3 to 5 times a week ☐ 5 or more times a week ☐ I choose not to answer this question Z60 Problems related to social environment Z60.0 Problems of adjustment to life-cycle transitions Z60.3 Acculturation difficulty Z60.4 Social exclusion and rejection Z60.5 Target of (perceived) adverse discrimination/persecution Z60.8 Other problems related to social environment Z62.2 Upbringing away from parents Z62.22 Institutional upbringing Z59.2 Discord with neighbors, lodgers, and landlord
Comments	Social relationships impact health as much or more than some major biomedical and behavioral factors. Social integration, or the number of relationships and frequency of contact, has more evidence supporting its role in health outcomes than subjective measures of loneliness (IOM, Phase I & II Report, 2014). Social isolation can present serious negative mental and behavior outcomes to anyone's health.
Use Case	The Use Case for isolation is to understand an individual social support. This is important for all aspects of care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

11.Stress	
Requirement Level	Must Have
Value set	[PRAPARE] Stress is when someone feels tense, nervous, anxious, or can't sleep at night because their mind is troubled. How stressed are you? ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much ☐ I choose not to answer this question Z72.4 Inappropriate diet and eating habits Z56 Problems related to employment/ unemployment Z56.0 Unemployment Z56.1 Change of job Z56.2 Threat of job loss Z56.3 Stressful work schedule Z56.4 Discord with boss and workmates Z56.5 Uncongenial work environment Z56.6 Other physical and mental strain related to work Z59.0 Homelessness Z59.2 Discord with neighbors, lodgers, and landlords Z60 Problems related to social environment Z60.0 Problems of adjustment to life-cycle transitions Z60.3 Acculturation difficulty Z60.8 Other problems related to social environment Z65.4 Victim of crime and terrorism Z65.5 Exposure to disaster, war, and other hostilities Z59.5 Extreme Poverty (100% FPL or below) Z59.6 Low income (200% FPL or below)
Comments	The measurement of stress is important to identify ongoing stressors, but also to understand the patient disposition and presentation.
Use Case	Stress has negative health consequences when a patient has insufficient resources to cope with it. Long-term exposure to chronic or severe stressors increases a patient's allostatic load, which is the biological mechanism by which stress produces negative health outcomes. Stress management interventions can prevent stress from becoming toxic to the body and contributing to the development of chronic health conditions (IOM, Phase I Report, 2014). The Use Case for stress is to capture the patient disposition. This is important for primary and urgent care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

12. Incarceration History

Requirement Level	Must Have
Value set	[PRAPARE] In the past year, have you spent more than 2 nights in a row in a jail, prison, detention center, or juvenile correctional facility? ☐ Yes ☐ No ☐ I choose not to answer this question Z56.0 Conviction in civil and criminal proceedings without imprisonment Z65.1 Imprisonment and other incarcerations
Comments	Incarceration is a risk factor for many chronic conditions such as HIV and Hepatitis C
Use Case	Legal problems are inextricably linked to health problems. Oftentimes, people are made ill or have their access to healthcare threatened because laws are not enforced or poorly written, and because benefits are wrongfully denied. (National Center for Medical-Legal Partnership) The Use Case for incarceration is to improve the collection of risk factor and comprehensive SDOH. This is important for all aspects care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

13. Safety

Requirement Level	Must Have
Value set	[PRAPARE] Do you feel physically and emotionally safe where you currently live? ☐ Yes ☐ No ☐ Unsure ☐ I choose not to answer this question
Comments	Exposure to unsafe environments and violence is a known contributing factor to mental health and well-being and can lead to other chronic conditions such as heart disease and stroke. Providing access to resources for support and actively creating & engaging in preventative practices will allow for a safer, healthier livelihood.
Use Case	The use cases for this safety data elements are to assist health care providers identify early indicators of patients in unsafe environments. This is important for referral to social care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

14. Domestic Violence

Requirement Level	Must Have
Value set	[PRAPARE] Do you feel physically and emotionally safe where you currently live? ☐ Yes ☐ No ☐ Unsure ☐ I choose not to answer this question In the past year, have you been afraid of your partner or ex-partner? ☐ Yes ☐ No ☐ I have not had a partner in the past year ☐ I choose not to answer this question Z63 Problems related to primary support group, includes family circumstances Z63.9 Problems in relationship with spouse or partner Z91.41 Personal history of adult abuse Z91.410 Personal history of adult physical and sexual abuse Z62.81 Personal history of abuse in childhood Z62.810 Personal history of physical and sexual abuse in childhood

	Z62.811 Personal history of psychological abuse in childhood Z62.812 Personal history of neglect in childhood
Comments	In the United States 1 in every 5 women and 1 in 7 men will become a victim of domestic violence. This issue has implications to all aspects of health care, from ability to attend visits, to concerns for security and disclosure. Collecting this data would allow for individuals to better set up appropriate interventions to this issue.
Use Case	Domestic violence affects both mental health and physical health and safety, and can lead to other chronic conditions such as heart disease and stroke. Providing access to resources for support and actively creating & engaging in preventative practices will allow for a safer, healthier livelihood. The Use Case for partner violence is to accurately portray this issue and to develop better interventions for solving it. This is important for primary care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

15.Refugee Status	
Requirement Level	Must Have
Value set	[PRAPARE] Are you a refugee? ☐ Yes ☐ No ☐ I choose not to answer this question
Comments	Refugees are at serious risks for being underserved medically. They additionally survey from an amalgamation of other SDOH such as language barriers, housing instability, occupational risk
Use Case	Health care providers need to be aware of, and sensitive to, cultural diversity, life situations, and other various factors that shape a person's identity to provide safe and quality care to all patients. These factors include refugee status, among other factors. (CDC, Cultural Diversity and Considerations) The Use Case for refugee is to provide competent and sensitive care to this key population. This is important for all aspects care as well as for both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

Appendix B: Sexual Orientation and Gender Identity (SOGI)

1. Sexual Orientation	
Requirement Level	Must Have
Value set	Lesbian or Gay, Straight, Bisexual, Something else, Don't know, Chose not to disclose
Comments	The USCDI does not have SOGI as a requirement, however ISA has these defined and several federal reporting systems, including HRSA's Uniform Data System (UDS) and Ryan White HIV/AIDS Program Services Report (RSR) require this data to be submitted
Use Case	The Use Case for sexual orientation is to identify LGB patients and provide competent sensitive care. This is important for ensuring LGBTQ individuals receive appropriate care as well as for both research and public health use cases.
Related Materials	https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-services-report-rsr https://hab.hrsa.gov/program-grants-management/data-reporting-requirements-and-technical-assistance

2. Gender Identity	
Requirement Level	Must Have
Value set	Male, Female, Transgender Male/Female-to-Male, Transgender Female/Male-to-Female, Other, Chose not to disclose
Comments	The USCDI does not have SOGI as a requirement, however ISA has these defined, and several federal reporting systems, including HRSA's Uniform Data System (UDS) and Ryan White HIV/AIDS Program Services Report (RSR) require this data to be submitted
Use Case	The Use Case for Gender Identity is to improve the delivery of transgender primary care_. This is important for ensuring the health care system is able and competent in providing trans care, as well as non-binary care as well as for both research and public health use cases.
Related Materials	https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-services-report-rsr https://hab.hrsa.gov/program-grants-management/data-reporting-requirements-and-technical-assistance

Appendix C: Women's Health – Pregnancy Status

Pregnancy Status Class

Comment on the class: ACOG supports the comment already made supporting HL7s CCDA "Pregnancy Status" as it is comprehensive in this area and would better support both clinical research and public health use cases.

https://www.hl7.org/implement/standards/product_brief.cfm?product_id=494

<u>Items:</u>
1. Pregnancy Status
2. Date Pregnancy Status
3. Estimated Delivery Date (EDD)
4. EDD Determination Method
5. Gestational Age
6. Date Gestational Age Determined
7. Gestational Age Determination Method
8. Pregnancy Outcome
9. Pregnancy Outcome Date
10. Any pregnancy outcome within the last 42 days?
11. LMP (Last Menstrual Period)
12. Multiplicity of birth/pregnancy

4. Pregnancy Status	
Requirement Level	Must Have
Value set	Yes, No, Unknown, currently pregnant or confirmed pregnant, not currently pregnant or pregnancy refuted, recently pregnant, possibly pregnant.

Comments	• Values have unnecessary overlap. Clinically the importance is around confirmation of pregnancy. ACOG recommends five values in this value set:
	    - Yes, confirmed pregnant;
	    - No, confirmed not pregnant;
	    - Unknown, possibly pregnant;
	    - Recently pregnant within the last 12 months
	
	ACOG recommends that "recently pregnant" be defined as within the last 12 months to capture pregnancy related complications. Importantly, pregnancy-related deaths may occur well beyond the early postpartum period,
	
	Per the CDC:
	
	"A pregnancy-related death is defined as the death of a woman while pregnant or within 1 year of the end of a pregnancy –regardless of the outcome, duration or site of the pregnancy–from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes."
	
	• ACOG supports a new data class called "Pregnancy Episode" of which pregnancy status would be a data element. Pregnancy Episode would have data elements that include a start and end date, pregnancy status, postpartum period, and a lactation period if relevant. End date of

	pregnancy would be defined both by an actual known date and be defined by a calculation off EDD such that the Pregnancy Episode would automatically close at a specified period of time post the EDD.
Use Case	The Use Case for Pregnancy Episode is to ensure that a status of pregnancy is accurate and not reflective of a pregnancy that took place in the past. It is also important to ensure that multiple pregnancies within a given time period are accurately reflected. This is important for clinical care as well as for both research and public health use cases.
ACOG Related Materials	CO736	Optimizing Postpartum Care (05/2018)
Requirement Level	Nice to Have
Value set	Patient reported, pregnancy test, urine-based pregnancy test, serum-based pregnancy test, ultrasound, clinical impression, history of hysterectomy other.
Comments	ACOG questions the need for these 'nice to have' values under pregnancy status as they are duplicative of values that exist elsewhere. Pregnancy tests and ultrasound are already covered in the Laboratory and Procedures Class and thus do not have a need to be restated here. History of hysterectomy more appropriately belongs with a designation of medically unable to conceive. Patient reported is a general health concern. Clinical impression is covered by yes, confirmed pregnant.

2. Date Pregnancy Status

Requirement Level	Must Have
Value Set	Date
No ACOG comments.	

3. Estimated Delivery Date (EDD)

Requirement Level	Must Have if pregnant, preferred
Value Set	Date
Comments	- The correct clinical terminology is Estimated Due Date, not Estimated Delivery Date - EDD and GA are calculations of one another and thus appropriately belong together as in that if you have one, you have the other. As such they need to be treated the same by USCDI in terms of "must have"/"nice to have", the difference being that they have two different value sets. EDD is a "Must Have" as an alternative to GA; GA is a "Must Have" as an alternative to EDD.
ACOG Related Materials (ReVITALize)	Obstetrics Data Definitions: Estimated Due Date (EDD): The best EDD is determined by last menstrual period if confirmed by early ultrasound or no ultrasound performed, early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or known date of fertilization (e.g., assisted reproductive technology).

4. EDD Determination Method	
Requirement Level	Nice to have if EDD used
Value Set	LMP, ultrasound first trimester, ultrasound second trimester, ultrasound third trimester, ultrasound, Ovulation date, Embryo transfer, Other.

Comments	• The determination method is a "Must Have" for both EDD and GA. The method reflects on the accuracy of the resulting date and is critical information to capture. Being able to assess the reliability of the EDD/GA directly impacts clinical management of a pregnant individual; being unable to assess reliability represents a patient safety issue for both the mother and fetus.
	Value set comments:
	• ACOG recommends the following value set for EDD determination method:
	    ○ LMP
	    ○ Earliest ultrasound date and gestation age in weeks/days
	    ○ First trimester ultrasound
	    ○ Second trimester ultrasound
	    ○ Third trimester ultrasound
	    ○ Ultrasound, unknown trimester
	    ○ Ovulation date
	    ○ Embryo transfer date
	    ○ Intrauterine insemination date
	    ○ Other

ACOG Related Materials	• ACOG Committee Opinion #700 Methods for Estimating the Due Date (05/2017) • ACOG Committee Opinion #688 Management of Sub-optimally Dated Pregnancies (03/2017) • ACOG Committee Opinion #671 Perinatal Risks Associated with Assisted Reproductive Technology (09/2016)

5. Gestational Age	
Requirement Level	Must Have if Pregnant alternative to EDD
Value Set	Number with units = weeks or days
Comments	Should be weeks AND days, not weeks OR days
ACOG Related Materials (ReVITALize)	Obstetrics Data Definitions: Gestational age (written with both weeks and days; e.g., 39 weeks and 0 days) is calculated using the best obstetrical EDD based on the following formula: gestational age = (280 - (EDD - Reference Date))/ 7

6. Date Gestational Age Determined	
Requirement Level	Must have if GA is used
Value Set	Date
No ACOG comments.	

7. Gestational Age Determination Method

Requirement Level	Must have if GA is used
Value Set	Ultrasound, EDD, ovulation date, OTHERS?
Comments	Dates should be supplied with the determination method as done with EDD determination method. The same value set may be used as EDD determination method: Embryo transfer, Ovulation date, ultrasound, ultrasound third trimester, ultrasound second trimester, ultrasound first trimester, LMP, Other, with the same comment above with dates added (embryo transfer date, ultrasound dates). Intrauterine Insemination needs to be added to the value set.

8. Pregnancy Outcome

Requirement Level	Nice to have if postpartum status is yes
Value Set	Molar pregnancy, elective termination, spontaneous termination <20 weeks gestation, still birth, ectopic/tubal, live birth, unknown, other, not a live birth

Comments	• This should be a "Must Have" as pregnancy outcome impacts care both in the short term and management of future pregnancies
	• ACOG proposes the current proposed value set be replaced with: Live birth, Gestational Trophoblastic Disease, elective termination, early pregnancy loss (<13 weeks), early second trimester loss[1] (loss <20 weeks), stillbirth/fetal death (20 weeks or greater), ectopic/tubal, term birth, preterm birth, unknown, other. Justification:
	   o Molar pregnancy should be replaced with Gestational Trophoblastic Disease as the more correct clinical terminology.
	   o "Not a live birth" should be removed as other values cover this value.
	   o In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss are used interchangeably; ACOG prefers the term 'early pregnancy loss' to reflect these events, and recommends it be added to the value set. "Spontaneous termination < 20 weeks gestation" should be removed.
	   o Fetal death is widely used and thus ACOG recommends that the value be stillbirth/fetal death to reflect this.
	   o The value set should add premature delivery and term birth as both are important to clinical care, research and public health use cases.
	• The Pregnancy Outcome must have the outcome date associated with it as metadata. A stand-alone Outcome Date risks not associating the correct pregnancy episode with that outcome. As such they must be linked together.

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[1] The term 'early' second trimester loss is being used to reflect the time period of 13 weeks to 19 6/7 weeks during the second trimester. Prior to 13 weeks 'early loss' should be used and after 20 weeks 'stillbirth/fetal death' applies.

ACOG Related Materials	• ACOG Practice Bulletin #200	Early Pregnancy Loss (08/2018): *Early pregnancy loss* is defined as a nonviable, intrauterine pregnancy with either an empty gestational sac or a gestational sac containing an embryo or fetus without fetal heart activity within the first 12 6/7 weeks of gestation.
	• ACOG Obstetric Care Consensus #10	Management of Stillbirth (03/2020): The U.S. National Center for Health Statistics defines *fetal death* as the delivery of a fetus showing no signs of life as indicated by the absence of breathing, heartbeats, pulsation of the umbilical cord, or definite movements of voluntary muscles. There is not complete uniformity among states with regard to birth weight and gestational age criteria for reporting fetal deaths. However, the suggested requirement is to report fetal deaths at 20 weeks or greater of gestation (if the gestational age is known), or a weight greater than or equal to 350 grams if the gestational age is not known. The cutoff of 350 grams is the 50th percentile for weight at 20 weeks of gestation. To promote the comparability of national data by year and state, U.S. vital statistics data are collected for fetal deaths with a stated or presumed period of gestation of 20 weeks or more. Terminations of pregnancy for life-limiting fetal anomalies and inductions of labor for previable premature rupture of membranes are specifically excluded from the stillbirth statistics and are classified as terminations of pregnancy
	• ACOG Practice Bulletin #143	Medical Management of First-Trimester Abortion (03/2014)
	• ReVITALize: Gynecology Data Definitions

9. Pregnancy Outcome Date	
Requirement Level	Must have if postpartum status is yes
Value Set	Date
Comments	• The Pregnancy Outcome Date must have the Pregnancy Outcome linked to it. A standalone Outcome Date risks not associating the correct pregnancy episode with that outcome. As such they must be linked together.
	• Pregnancy Outcome Date must also include the level of certainty in the date {certain, estimated, unknown} as some outcomes, particularly with ectopic and early pregnancy loss, may not have a known outcome date.
	• The requirement level is a "Must Have" when there is *any* "Pregnancy Outcome", not just postpartum status of yes. Not all pregnancies result in a postpartum state, such as an ectopic pregnancy.

10. Any pregnancy outcome within the last 42 days?	
Requirement Level	Must have if not pregnant
Value Set	Yes, no, unknown
Comments	• ACOG proposes that the data element of "Any pregnancy outcome within the last 42 days?" be replaced with the data element of "Not Pregnant", with an expanded value set . The data element of "Any pregnancy outcome within the last 42 days?" is covered by data element number 8: "Pregnancy Outcome". What is missing from the Pregnancy Status Class is a specific data element of "Not Pregnant" • Value set for "Not Pregnant": LMP, method of contraception, pregnancy intention, pregnancy prevention intention-reported, medically unable to conceive {hysterectomy, inability to conceive with current partner, bilateral oophorectomy, bilateral salpingectomy, genetically unable to conceive, menopause}. • ACOG recommends the Pregnancy Intention value set include the values specified by LOINC 86645-9: Yes, I want to become pregnant; I'm OK either way; No, I don't want to become pregnant; Unsure • ACOG recommends the Pregnancy Prevention Intention -Reported value set include the values specified by LOINC 91144-6: I am already doing something to prevent pregnancy; I want to start preventing pregnancy; I don't want to prevent pregnancy; I am unsure whether I want to prevent pregnancy; I prefer not to answer; This question does not apply to me.
Use Case	Support of clinical decision support (CDS) for medication prescribing; necessary data elements to support research which may require confirmation of protection against pregnancy.
LOINC Details	Pregnancy prevention intention – Reported has existing LOINC codes. LOINC Term Description: A patient's current intentions to prevent pregnancy. This includes a male patient's intentions to prevent pregnancy with a female partner. This term was created for, but not limited in use to, the Office of Population Affair's (OPA's) clinical performance measures for contraceptive provision endorsed by the National Quality Forum (NQF). https://loinc.org/91144-6/ Pregnancy Intention is a component of the LOINC Pregnancy and Contraception Panel 86642-6 (FPAR) Family Planning Annual Report. LOINC Term Description: A patient's intention or desire in the next year to either become pregnant or prevent a future pregnancy. This includes male patients seeking pregnancy with a female partner. Pregnancy intention may be used to help improve preconception health screenings and decisions, such as determining an appropriate contraceptive method, taking folic acid, or avoiding toxic exposures such as alcohol, tobacco and certain medications. This term was based on, but is not limited in use to, Power to Decide's One Key Question®, used by the Office of Population Affair's (OPA's) Family Planning Annual Report (FPAR). https://loinc.org/86645-9/

11. LMP (Last Menstrual Period)

Requirement Level	Nice to have alternate to EDD/GA not dependent on pregnant
Value Set	Date
Comments	• Last menstrual period (LMP) should be a "Must Have" and not a "Nice to Have" as a data element. LMP remains important in determining EDD/GA along with the first accurate ultrasound or both. • Value set, in addition to date, should include certain, estimated, unknown, N/A. N/A should have the ability to include the reason for no menses {pre-menarcheal, hormonal suppression, breastfeeding, hysterectomy, endometrial ablation}.
ACOG Related Materials	• ReVITALize: Obstetrics Data Definitions: Estimated Due Date (EDD): The best EDD is determined by last menstrual period if confirmed by early ultrasound or no ultrasound performed, early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or known date of fertilization (e.g., assisted reproductive technology). • ACOG Committee Opinion #700 Methods for Estimating the Due Date (05/2017)

12. Multiplicity of birth/pregnancy

Requirement Level	Nice to have
Value Set	Numeric
Comments	• Multiplicity of birth/pregnancy should be a "Must Have" and not a "Nice to Have" data element. Twins and higher order pregnancies have an increase in fetal morbidity and mortality, primarily due to prematurity. Because of the increase in adverse outcomes with non-singleton pregnancies, it is important to capture this data for both clinical research and public health use cases.
ACOG Related Materials	• Practice Bulletin #169 Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancies (10/2016)