Julia Skapik, MD, MPH, FAMIA
Chief Medical Information Officer
National Association of Community Health Centers
7501 Wisconsin Ave, Suite 1100W
Bethesda, MD 20814

April 15, 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

Re**:** Draft United States Core Data for Interoperability Version 5 (Draft USCDI v5)

Dear Dr. Tripathi:

The National Association of Community Health Centers (NACHC) welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability Version 5 (Draft USCDI v5), and to participate in advancing USCDI. 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.

We encourage ONC and its federal partners 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. NACHC has been working with partner health centers and across industry to understand challenges to the deployment of USCDI requirements and implementation of the data capture and quality it requires. Community health centers routinely have experienced certified systems that are not in practice, conformant to all the certified functionalities and data requirements and are often the last customers to receive updates to conform to new requirements. We believe that more effort to ensure that underserved communities and health equity populations receive timely access to these important advances in data standardization and interoperability is a key component to addressing health disparities and improving digital health access.

Additional support for critical areas of primary care services in USCDI are key for advancing national strategic priorities like reducing maternal morbidity and mortality, ending the HIV and Hepatitis C epidemics, addressing gender-affirming and reproductive health care, addressing social determinants and drivers of health (SDOH) and improving care coordination. Ending the exception around implanted reproductive health devices would address a longstanding inequity around interoperability and data exchange for intrauterine devices (IUDs) and implanted contraceptives and NACHC urges ONC to consider this step. Support for a comprehensive data model centered around the pregnancy and postpartum episodes would better support care teams in primary care obstetrics; this approach is already implemented in several health center-controlled networks and has led to better and more accurate data on pregnancy outcomes including the actual delivery date, which is needed to drive timely patient follow-up and quality improvement efforts. Improving required laboratory metadata and enriching social history

elements around risk behaviors could allow more comprehensive sharing of data on HIV and Hepatitis C status that drives the respective care cascades for these infectious conditions.

Finally, we encourage ONC to treat SDOH as a cross-cutting data class rather than a unique one, in that SDOH includes existing and emerging data elements across multiple data classes present in USCDI, such as demographics, health status, social needs, social history and diagnoses. A filtering element in USCDI could allow data elements to be designated both in the class in which they reside and as elements required to support social needs and services.

Additional data elements in USCDI widen the scope of agreement for a common representation of data, with standards widely available and accessible, supporting semantic aggregation for research and interoperability. 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. However, the creation of new domains in USCDI+ does potentially create a risk for lack of alignment across this important program. NACHC encourages ONC to require all USCDI+ data elements to at a minimum, be aligned to the content in the core USCDI standard. Ideally, new metadata elements and content in USCDI+ would then be pushed through to the USCDI standard over time.

NACHC encourages ONC to consider going farther to build formal data models and to extend required metadata in USCDI in advance of comment periods to avoid the spread of comments which fail to have the specificity needed to ensure machine to machine readability. Creating and optimizing bidirectional test environments for the successful testing of USCDI and USCDI+ as well as sample datasets are likely to assist and accelerate the process for implementation and would be of strong interest and utility in the health center community. These could become updates to the EHR certification protocols and also foster more conformant data tools and products in the community.

NACHC looks forward to the ongoing maturity of this program and appreciates the opportunity to provide comments.

Sincerely,

Julia Skapik, MD, MPH, FAMIA
CMIO
National Association of Community Health Centers

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

HL7 USCDI Responses [Including Draft USCDI v5 New Data Classes and Elements]

Care Team Member: Identity

https://www.healthit.gov/isa/taxonomy/term/1291/draft-uscdi-v5

HL7 notes that California and Colorado law require that caregivers to record their identity in a public facing provider directory, which is an important consideration. More information specific to California can be accessed at:
https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=202120220SB923&showamends=false

Clinical Notes: Emergency Department Note [New Data Element]

https://www.healthit.gov/isa/taxonomy/term/7786/draft-uscdi-v5

HL7 observes that adding additional Clinical Notes data elements could open the door to many new Notes Document Types to be added. This could create disparate documents and should be carefully considered.

Health Status Assessments: Mental/Cognitive Status

https://www.healthit.gov/isa/taxonomy/term/1616/draft-uscdi-v5

HL7 recommends that Depression Assessment listed under Health Status Assessment as an example screening of interest, recognizing that not all health information technology (HIT) may need to support that when being certified. Depressive disorders are common mental disorders that occur in people of all ages. Major depressive disorder (MDD) is the second leading cause of disability worldwide, affecting an estimated 120 million people. Depression has a large effect on health care costs and on productivity. Adolescents with depression have higher medical expenditures, including those related to general and mental health care, than adolescents without depression. For working-adults, one study showed a relationship between the severity of depression symptoms and work function and found that for every 1-point increase in a Patient Health Questionnaire 9 (PHQ-9) score (a measure of depression severity); patients experienced an additional mean productivity loss of 1.65%. Even minor levels of depression symptoms were associated with decreases in work function. The U.S. Preventive Services Task Force (USPSTF) recommends screening for depression among adolescents 12-18 years and the general adult population, including pregnant and postpartum women.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

Health Status Assessments: Smoking Status

https://www.healthit.gov/isa/taxonomy/term/811/draft-uscdi-v5

HL7 recommends changing the name of Smoking Status to Tobacco Assessment and Use. Not all tobacco products are combustible like cigarettes. This category should include the noncombustible products as well, such as e-cigarettes. Both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) refer to the broader category of Tobacco Use. Please see:

https://www.cdc.gov/chronicdisease/resources/publications/factsheets/tobacco.htm
https://www.fda.gov/consumers/minority-health-and-health-equity-resources/tobacco-use

In addition, HL7 recommends duration (number of years of use) and quit date included in the list of example data elements. The duration is used to calculate the number of pack years, which is important for quality measurement and understanding risk. In addition, knowledge about when someone quit smoking helps to understand risk for other diseases.

Health Status Assessments: Social Determinants of Health (SDOH) Assessment

https://www.healthit.gov/isa/taxonomy/term/1801/draft-uscdi-v5

HL7 applauds the inclusion of SDOH elements in USCDI. HL7 supports moving SDOH to its own data class with SDOH Problems/Health Concerns and SDOH Interventions as data elements. The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP) and the American Dental Association (ADA) all recommend surveillance of risk factors associated with SDOH. Designating a distinct SDOH category emphasizes its critical importance. HL7 provides in the SDOH Clinical Care Implementation Guide a number of assessment and screening tools that should be considered by implementers of USCDI where they are relevant to their user community. More information can be found at: https://build.fhir.org/ig/HL7/fhir-sdoh-clinicalcare/.

Laboratory: Specimen Condition Acceptability

https://www.healthit.gov/isa/taxonomy/term/7691/draft-uscdi-v5

HL7 notes that with the introduction of Specimen Condition Acceptability in USCDI v4 there has been confusion about what exactly is intended to be included: either the condition of the specimen as-is, or the reason why a test was not performed given the acceptability of the specimen, also known as Criteria for CLIA Specimen Acceptability and Rejection. HL7 notes that various conditions of a specimen (e.g. lipemia) may not prevent a test from being performed, while other conditions make the specimen unacceptable for any test (e.g., compromised/broken tube). HL7 recommends that ONC update the name of Specimen Condition Acceptability to Specimen Condition and update the definition to reflect the focus on the actual specimen condition. This would align with the actual implementation of this concept in both HL7 FHIR US Core 7.0.0, HL7 Clinical Document Architecture (CDA) and HL7 Consolidated Clinical Document Architecture (C-CDA). We also ask that ONC applies this to USCDI v4 as an errata, clarifying intent, to ensure that those reviewing and interpreting USCDI v4 without reviewing the supporting FHIR US Core and implementation guides for CDA and C-CDA do not yield different expectations, than those implementing the FHIR US Core and implementation guides for CDA and C-CDA.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

Laboratory: Tests [General]
https://www.healthit.gov/isa/taxonomy/term/676/draft-uscdi-v5

HL7 notes that the name does not differentiate between the test that was ordered versus the test that was performed. HL7 recommends updating the name to "Laboratory Performed Test Code" and clarifying the binding to be to “LOINC: Lab class (Obs only or Both).”

Laboratory: Tests [Panel Code]
https://www.healthit.gov/isa/taxonomy/term/676/draft-uscdi-v5

HL7 recommends that that Laboratory Test/Panel Code in Level 2 could be elevated to USCDI v5, but only if the name and definition are updated as listed below. Update the name to "Ordered Laboratory Test / Panel Code"

- Update the definition to "A code that identifies the test or group of tests (panel or profile), including reflexive tests being ordered for the analysis on a specimen derived from humans, which provide information for the diagnosis, prevention, treatment of disease, or assessment of health."

This will correspond to the coded version of the CLIA element in §493.1291(c)(4).

This change will also provide better clarity since the current name is misleading and given there are no results for any orders such as a panel. The change also provides improved distinction with the element "Tests" when that is updated as proposed in our Tests comments.

Laboratory: Test Kit Unique Device Identifier (UDI) [New Data Element]
https://www.healthit.gov/isa/taxonomy/term/3731/draft-uscdi-v5

HL7 notes that the definition is referencing UDI and the name includes "unique". Relevant standards and guidance such as HL7 Version 2 (HL7 v2), Integrating the Healthcare Enterprise Laboratory Analytical Workflow (IHE LAW), HL7 FHIR US Core, HL7 Clinical Document Architecture (CDA) and HL7 Consolidated Clinical Document Architecture (C-CDA) can use the full UDI as defined by the FDA for certain, limited use cases. However, the necessary guidance to support it -- from the source instrument all the way to systems such as electronic health records (EHRs) and those in public health -- are not yet attainable in practice. The full UDI of the test kit or the instrument (where applicable) is not a reality. The following are challenges that must be addressed:

- The laboratory may have some of the UDI components on paper but not necessarily all, and typically not electronically within their laboratory information systems (LIS).
- The relevant HL7 v2 standards and IHE LAW profiles support some of the requirements, but not all requirements to fully enable instruments and LIS to communicate the necessary UDI components. Even just the name and model of the instrument with a manufacturer name and/or the name of the test kit/reagent and manufacturer is a challenge. Specifically:
    - IHE Law profiles are not widely adopted by instrument manufacturers and LIS vendors.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

  - While those using IHE LAW include an instrument name and/or model, the formal Device Identifier is typically not included.
  - Guidance on correctly including UDI components into the appropriate IHE LAW profile fields is insufficient.
  - Guidance on correctly including multiple UDIs (instrument plus test kit/reagents) for an individual test is insufficient within standards frameworks such as HL7 v2, IHE LAW, and profiles and Implementation Guides relating to Laboratory Results Information (LRI) and Electronic Lab Reporting (ELR). If only one can be communicated, which one should be included?
- It is unclear how the test kit / reagent UDI components can be electronically obtained in the LIS for a specific test, as an instrument can use different test kits/reagents from different manufacturers. Inherent challenges are: either the instrument cannot communicate which test kit/reagent is in use for a given test, and/or the LIS cannot assert which combination is being used for the test result received.
- Even if current standards are adopted for new instruments, older instruments would not support them.
- LIS does not typically store these elements nor make it available and usable for further reporting, thus it would not be possible to include these on the results report to the EHR or in Public Health.

Until the UDI components can be consistently populated in the LIS with the results and communicated to the ordering provider, public health, and/or other recipients, inclusion of the UDI or related components is premature.

However, recognizing the timeline by which USCDI v5 would start to be implemented, it is appropriate to consider inclusion of a minimum set of UDI components, followed by additional components in subsequent USCDI versions. ONC should also consider using USCDI+ Public Health (PH) Laboratory Reporting to include additional components as this would facilitate a more focused audience and could be used to incent laboratories and LIS in particular to support the necessary documentation and communication of the full UDI for test kit and instrument used.

Short term, HL7 therefore suggests that a focus on the name and model of the main instrument and its manufacturer (when an instrument is used) is applied. This can be followed over time with the name of the test kit/reagent and its manufacturer and progress towards the full UDI for both the test kit/reagent(s) and instrument used. Furthermore, HL7 suggests that ONC work with FDA, the Centers for Medicare and Medicaid Services staff responsible for implementing the Clinical Laboratory Improvement Amendments (CLIA), public health agencies, laboratories, and instrument manufacturers to establish a practical roadmap for adoption and the necessary incentives to achieve that. Having the source systems, e.g., instrument, test kit, and LIS, be able to share this information will enable receiving HIT (e.g., EHRs, Public Health) to provide support where needed. Additionally, an approach should be established for tests where UDI are not present, to understand what was used to perform the test.

Lastly, HL7 observes this related gathering UDI on test kits, whether the exchange would be captured across all healthcare entities (i.e., electronic medical records, Payer's State or Federal Agencies) should

be examined. Ensuring this cohesion is critical. Entities responsible for tracking and reporting this data should also be considered.

Laboratory: Values/Results [General]

HL7 notes that the definition and vocabulary of Values/Results focuses on qualitative values and results. The variances in vocabulary are notable particularly given the nominal scale uses SNOMED CT in organism hierarchy with example value set: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=64089FFA-B015-4DC7-B470-F20DF5B13BFA, while the ordinal scale uses SNOMED CT from a qualifier hierarchy: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=815C6DD4-C5A6-DF11-9BDD-0015173D1785). Additionally, the structure of quantitative results (e.g., relationship with the Result Unit of Measure) of interest should be further clarified.

Laboratory: Values/Results [Date and Timestamps]

https://www.healthit.gov/isa/taxonomy/term/681/draft-uscdi-v5

HL7 recommends that rather than listing a general date and timestamps, that the specific dates and timestamps of interest should be enumerated. HL7 specifically suggests elevating the following Level 2 data elements into USCDI v5:

- Specimen Collection Date/Time: The clinically relevant time - provides clinical temporal context about the state of the patient as it relates to the performed lab test. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of specimens obtained from the patient, it is the date and time, the specimen was collected in accord with CLIA.
- Laboratory Test Performed Date: The clinically relevant date/time of the observation. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field should represent the date and time the specimen was analyzed and results obtained. This is often the LIS verification date/time, whether by an automated process or via a human.
    - HL7 recommends adjust the definition to state: "Date (and optionally time) when testing was conducted by the laboratory performing the testing". This date is not necessarily the clinically relevant data/time as that would be the specimen collection date/time for lab tests. This date may be important when multiple tests are part of a report and is also helpful in identifying updated results, when only some results are updated in a report.

HL7 notes these dates are widely supported and available. We therefore support inclusion in USCDI v5. Additionally, HL7 recommends that Report Date/Time (similar to Date of Report in Case Reporting in USCDI+) is defined as “The date and time at which the LIS system releases the results to the provider and other recipients” which meets CLIA test report date as well, as a critical date and timestamp. This applies to any report, whether preliminary, final or corrected and is widely communicated already.

Observations (General) - [New Data Class]
https://www.healthit.gov/isa/uscdi-data-class/observations#draft-uscdi-v5

HL7 notes that the distinction between the new Observations data class and other data classes such as Laboratory and Vital Signs, is unclear considering Laboratory Test Results are categorized as Observations, as are Vital Signs. HL7 suggests that Vital Signs and Laboratory Test Results are included under Observations as references and also as specific data elements that are listed under Observations. This approach would provide greater clarity regarding to which other data classes they would apply.

Observations: Advanced Directive Observation [New Data Element]
https://www.healthit.gov/isa/uscdi-data-class/observations#draft-uscdi-v5

HL7 applauds the inclusion of an Advanced Directive Observation. We also encourage ONC to advance the Level 1 and Level 2 Advance Directive class, so as to more fully support the Advance Directive concept.

Observations: Sex Parameter for Clinical Use [New Data Element]
https://www.healthit.gov/isa/taxonomy/term/4611/draft-uscdi-v5

Overall, HL7 encourages ONC to align Sex Parameter for Clinical Use with the current HL7 Gender Harmony recommendations. Background information can be found at:

https://hl7.org/xprod/ig/uv/gender-harmony/background.html

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=564

HL7 highlights that the Sex Parameter for Clinical Use definition is ambiguous. HL7 recommends the Sex Parameter for Clinical Use definition be changed to reflect that this Observation provides guidance on how a recipient should apply settings or reference ranges and provide context for further interpretation of diagnostic tests. Also to be noted is that where relevant, the Sex Parameter for Clinical Use for a particular diagnostic test is derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.

Orders (General) - [New Data Class]
https://www.healthit.gov/isa/uscdi-data-class/orders#draft-uscdi-v5

HL7 notes that the distinction between the new Orders data class and other data classes such as Laboratory, Procedures, and Medication is unclear considering lab tests, procedures, and medications can all be ordered and a variety of the already defined data elements are relevant when ordered. HL7 recommends that the general Orders data class include data elements relevant across all order types. Individual data classes should reference these general data elements and their respective standards while adding data elements specific to that data class when being ordered.

HL7 highlights that the addition of orders in Draft USCDI v5 improves transition of care so that the receiving provider is aware of orders put in by the sending provider. HL7 observes one important

scenario to recognize and accommodate, is to ensure that orders for a patient going to a skilled nursing facility (SNF) are received in a timely manner and not lost. This is linked to critical implements and accommodations a patient could need on arrival at an SNF including medications, special diets, special bed, etc. This could also provide avenues for a patient or caregiver to trace back to what was ordered and compare to what was delivered, as well as a way a patient can show another organization what was ordered in case during the transition of care, the order was lost (for example, an order for pain medication for a cancer patient when transitioning from acute care to post-acute care).

Patient Demographics/Information: Interpreter Needed [New Data Element]

https://www.healthit.gov/isa/taxonomy/term/7903/draft-uscdi-v5

HL7 agrees that interpreters are needed and should be captured in provider electronic systems (i.e. EMR). Interpreters can assist providers with non-English-speaking patients in reviewing charts, scheduling appointments and care management.

HL7 observes that whether a patient needs an interpreter can also vary based on circumstance. For example, a Spanish-speaking patient that has an appointment with a specialist that only speaks English may need an interpreter. However, if that same patient has an appointment with their primary care physician who speaks Spanish, no interpreter would be necessary. Exchanging the patient's spoken language proficiency allows systems to determine whether a patient needs an interpreter for specific appointments or encounters based on the language proficiency of the other participants. The spoken language proficiency is the proposed alternative, rather than written language proficiency, as the existing "Preferred Language" data element enables systems to determine what language is preferred for written materials.

HL7 recommends that ONC:

- adopt "Spoken Language Proficiency" as a patient demographic.
- consider/clarify how "Interpreter Needed" should be used in cases where providers may offer different languages.
- clarify how "Interpreter Needed" relates to the existing "Preferred Language" data element.

Patient Demographics/Information: Name to Use [New Data Element]

https://www.healthit.gov/isa/taxonomy/term/4586/draft-uscdi-v5

HL7 supports the inclusion of Name to Use in USCDI. We note that existing HL7 standards already support the exchange of this information.

Additionally, HL7 highlights that payer and provider specific systems may or may not have these Name to Use data elements captured currently. There is notable variance.

Patient Demographics /Information: Pronoun [New Data Element]

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5

HL7 supports the inclusion of Pronouns in USCDI. Our additional recommendations on this issue include recommending ONC:

- adopt patient pronouns in USCDI as proposed.
- delegate the work of identifying and defining vocabulary standards to consensus-based groups, such as US Core, as the vocabulary standards for this element are relatively new.

Lastly, HL7 observes shared data should not replace a person's name, but may offer a supplement. Both names and pronoun are not widely used nor included within systems. HL7 recommends that Caregiver(s) should also be included as a source of pronoun information.

Provenance: Author and Author Role [New Data Elements]

https://www.healthit.gov/isa/taxonomy/term/1171/draft-uscdi-v5
https://www.healthit.gov/isa/taxonomy/term/2201/draft-uscdi-v5

HL7 applauds the addition of Author and Author Role so that now individual clinicians can be identified, as well as patients and their caregivers. The ability to recognize patients and caregivers as authors paves the way to including more patient contributed health data in a medical record. The ability to individually identify a data author provides richer information to patients. HL7 highlights one nuance to consider: if an author is external to an organization or leaves an organization, they might not have an organizational ID or system ID. Patients and caregivers would most likely also not have identifiers while clinicians may have an NPI/license number/certificate number. An author could potentially be a device as well, such as a patient's Fitbit. HL7 recommends that it be made more explicit in USCDI v5 that a device could author data.

In addition, the inclusion of new fields in the Provenance class can better enable communication of patient generated health data. However, in USCDI v5 as in v4, several of the new fields represent data types that might be especially sensitive to the patient. Some examples in V5 include Pronoun, Name to Use, and Sex for Clinical Use. ONC should consider appropriate protection of these specific data items, while balancing all healthcare stakeholder interests.

This section describes 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 - Date of Death**
3. **Patient Demographics - Tribal Affiliation**
4. **Health Insurance Information**
5. **Health Status – Functional Status**
6. **Health Status – Disability Status**
7. **Health Status – Mental Function / Mental Health Status and Cognitive Status**
8. **Health Status – Women's Health - Pregnancy Status / Pregnancy Episode and others**
9. **Laboratory – Specimen Type**
10. **Laboratory – Result Status**
11. **Social Determinants of Health (SDoH) Data Class and Domains**
12. **Social Determinants of Health (SDoH) Assessments**
13. **Social Determinants of Health (SDoH) Goals**
14. **Social Determinants of Health (SDoH) Problems / Health Concerns**
15. **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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF 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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

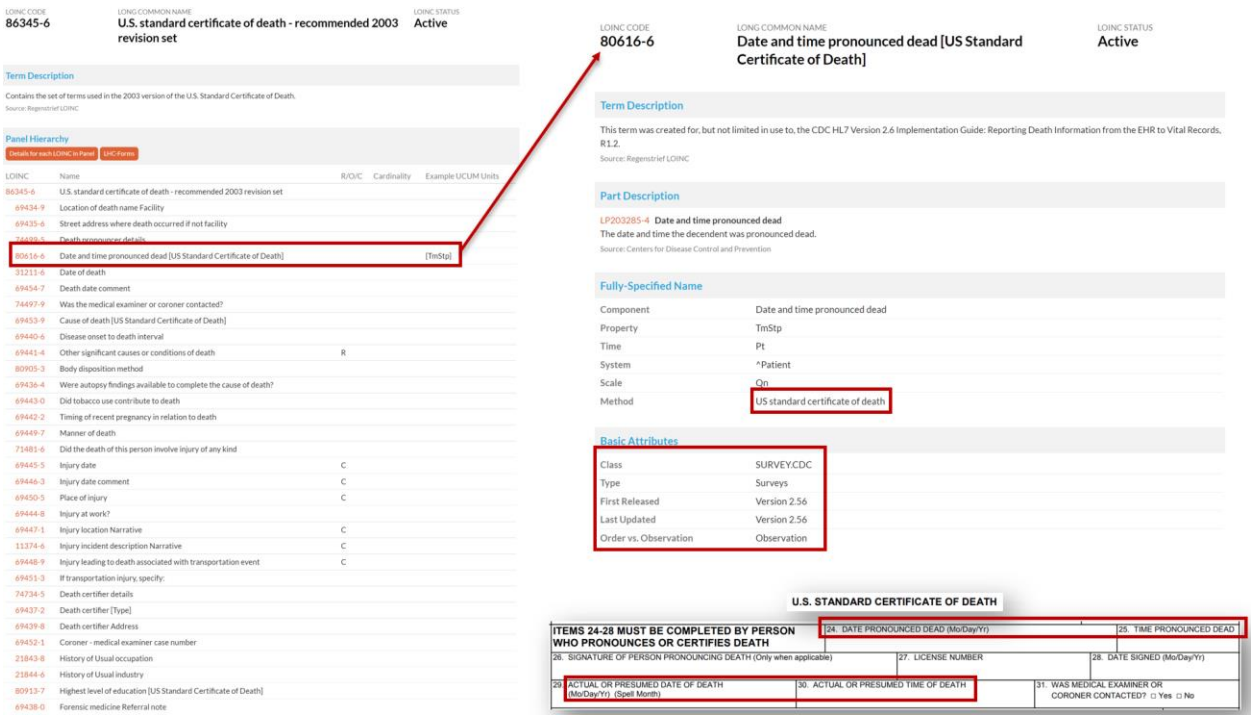
NATIONAL ASSOCIATION OF Community Health Centers®

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.



Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

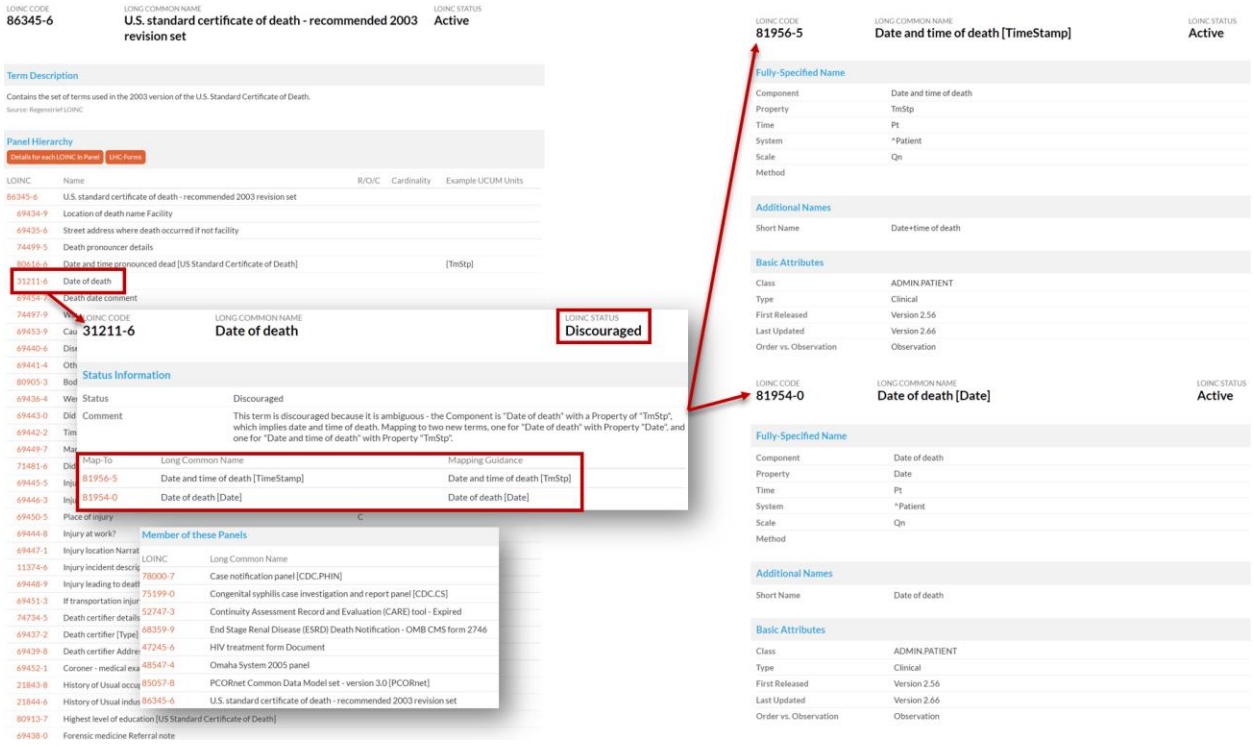
NACHC is sensitive to the fact that in some use cases a date of death may be available but not a time, and so suggests that the implementation guidance in this case addresses the situation in which date but not time are available by defaulting to a null time or by linking this code to the clinical date 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

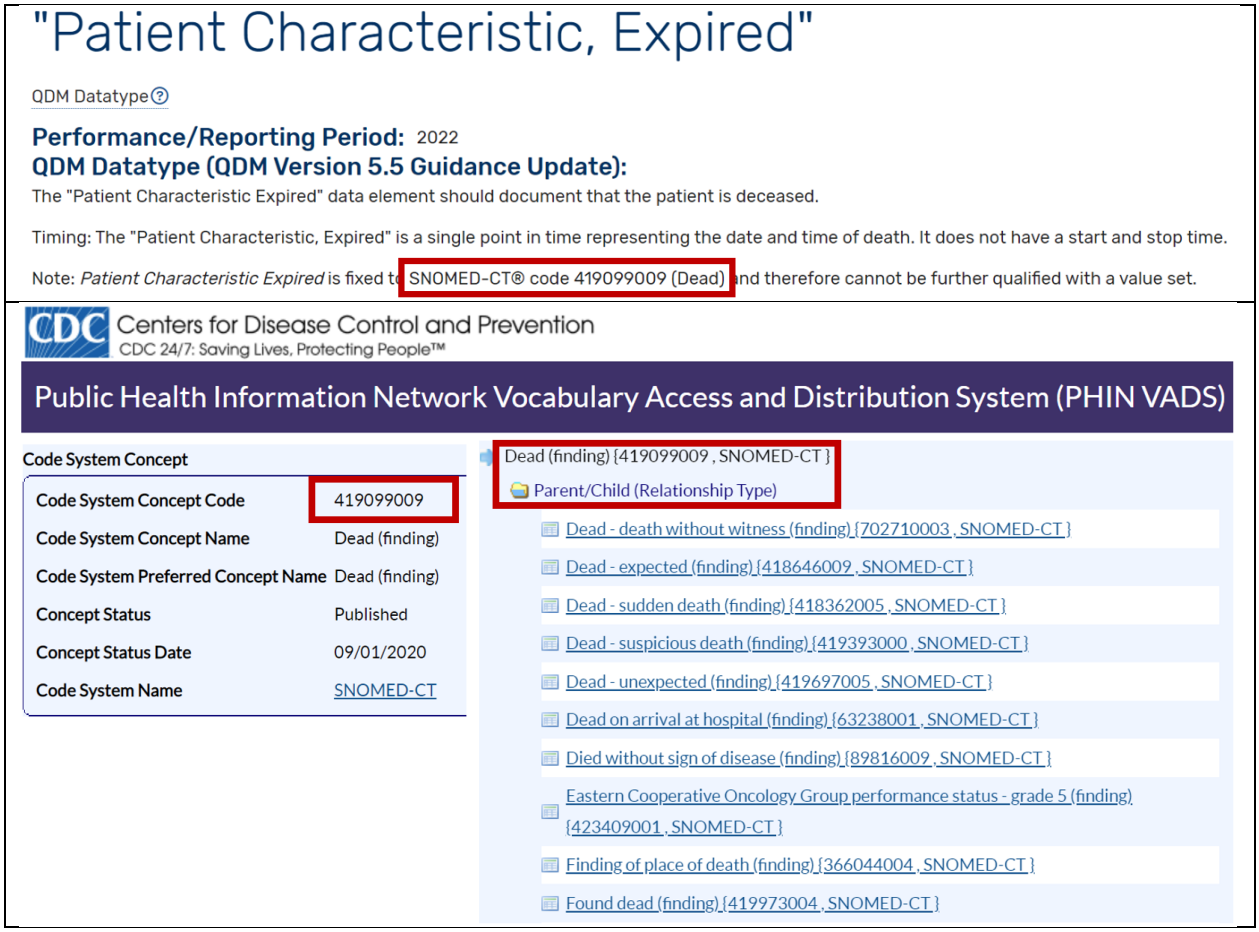


Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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 Characteristic, Expired"

QDM Datatype

Performance/Reporting Period: 2022

QDM Datatype (QDM Version 5.5 Guidance Update):

The "Patient Characteristic Expired" data element should document that the patient is deceased.

Timing: The "Patient Characteristic, Expired" is a single point in time representing the date and time of death. It does not have a start and stop time.

Note: *Patient Characteristic Expired* is fixed to SNOMED-CT® code 419099009 (Dead) and therefore cannot be further qualified with a value set.

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS)

Code System Concept

Code System Concept Code	419099009
Code System Concept Name	Dead (finding)
Code System Preferred Concept Name	Dead (finding)
Concept Status	Published
Concept Status Date	09/01/2020
Code System Name	SNOMED-CT

Dead (finding) {419099009 , SNOMED-CT }

Parent/Child (Relationship Type)

- Dead - death without witness (finding) {702710003 , SNOMED-CT }
- Dead - expected (finding) {418646009 , SNOMED-CT }
- Dead - sudden death (finding) {418362005 , SNOMED-CT }
- Dead - suspicious death (finding) {419393000 , SNOMED-CT }
- Dead - unexpected (finding) {419697005 , SNOMED-CT }
- Dead on arrival at hospital (finding) {63238001 , SNOMED-CT }
- Died without sign of disease (finding) {89816009 , SNOMED-CT }
- Eastern Cooperative Oncology Group performance status - grade 5 (finding) {423409001 , SNOMED-CT }
- Finding of place of death (finding) {366044004 , SNOMED-CT }
- Found dead (finding) {419973004 , SNOMED-CT }

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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 Chanega (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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

		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	Identify adverse pregnancy complications that can have lifelong effects on the pregnant individual's health, such as

	the health of the pregnant or postpartum person, the infant, or both.	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	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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

	care; and 9) other evidence-based recommendations for postpartum care services	

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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/

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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.

Core	
UDS SDH Domains	Non-UDS SDH Domains (MU-3)
1. Race	10. Education
2. Ethnicity	11. Employment
3. Veteran Status	12. Material Security
4. Farmworker Status	13. Social Isolation
5. English Proficiency	14. Stress
6. Income	15. Transportation
7. Insurance	
8. Neighborhood	
9. Housing Status and Stability	

Optional	
1. Incarceration History	3. Domestic Violence
2. Safety	4. Refugee Status

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.

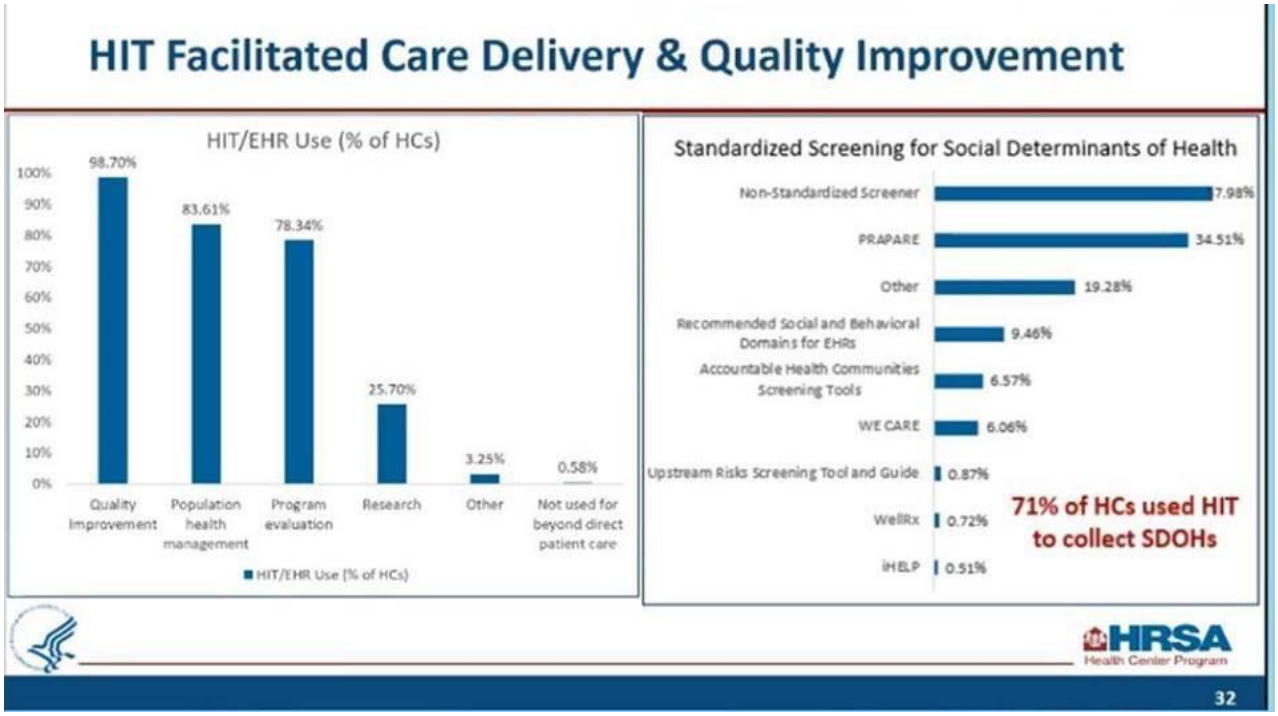


Figure 2 Distribution of EHR use-purpose in FQHCs (Left), distribution of SDOH collection tools (right)

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.

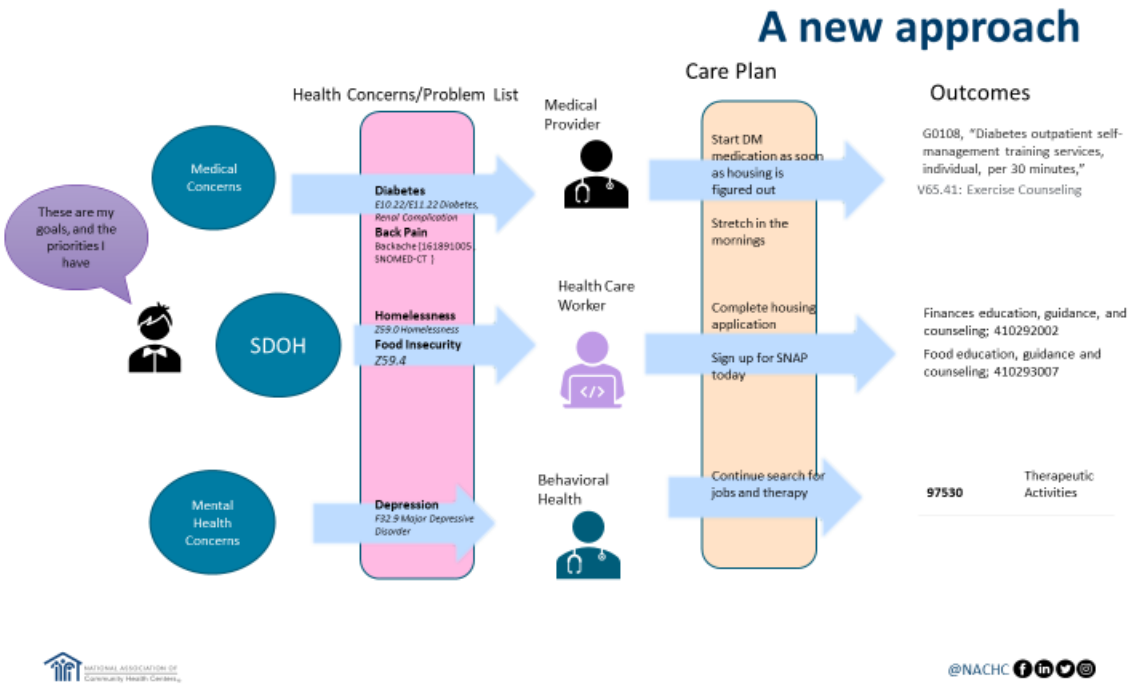


Figure 3 Theoretical framework for addressing ad caring for SDOH data in EHRs via eCare Planning

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)

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

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.

Core	
UDS SDH Domains	Non-UDS SDH Domains (MU-3)
1. Race	10. Education
2. Ethnicity	11. Employment
3. Veteran Status	12. Material Security
4. Farmworker Status	13. Social Isolation
5. English Proficiency	14. Stress
6. Income	15. Transportation
7. Insurance	
8. Neighborhood	
9. Housing Status and Stability	

Optional	
1. Incarceration History	3. Domestic Violence
2. Safety	4. Refugee Status

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/

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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/

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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/

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

NATIONAL ASSOCIATION OF Community Health Centers®

Appendix B: 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

Items:

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: o LMP o Earliest ultrasound date and gestation age in weeks/days o First trimester ultrasound o Second trimester ultrasound o Third trimester ultrasound o Ultrasound, unknown trimester o Ovulation date o Embryo transfer date o Intrauterine insemination date o 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.

[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.

Main Office
7501 Wisconsin Ave
Suite 1100W
Bethesda, MD 20814
301.347.0400 TEL
301.347.0459 FAX

Federal and State Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
703.739.7300 TEL
703.684.3629 FAX

www.nachc.org

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)