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

Dear National Coordinator Tripathi:

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

This document describes in its sections and appendices NACHC's feedback and support for the following data elements for which we are requesting additional support for interoperability definitions in USCDI version 3:

- 1. Patient Demographics Sexual Orientation & Gender Identity (SOGI)
- 2. Patient Demographics Date of Death
- 3. Patient Demographics Tribal Affiliation
- 4. Patient Demographics Occupation
- 5. Patient Demographics Occupation Industry
- 6. Health Insurance Information
- 7. Health Status Functional Status
- 8. Health Status Disability Status
- 9. Health Status Mental Function
- 10. Health Status Pregnancy Status | Women's Health
- 11. Vital Signs Average Blood Pressure
- 12. Laboratory Specimen Type

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- 13. Laboratory Result Status
- 14. Social Determinants of Health (SDoH) Data Class and Domains
- 15. Social Determinants of Health (SDoH) Assessments
- 16. Social Determinants of Health (SDoH) Goals
- 17. Social Determinants of Health (SDoH) Problems / Health Concerns
- 18. 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 in USCDIv3 such as SDoH and SOGI can inform care delivery, thereby addressing health disparities and empowering providers in achieving health equity. Health IT has, in the past, exacerbated health inequities; however, we believe it could instead 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.

Patient Demographics - Sexual Orientation & Gender Identity

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

SO/GI data can be collected in several ways:

1. Information can be obtained through patient portals and transmitted to an individual's EHR. This approach is attractive because it puts the patient in charge of defining their own identity and needs.

2. Questions can be included on registration forms for all patients as part of the demographic section along with information about race, ethnicity, and date of birth.

3. Providers and their care team can ask questions during the patient visit, for instance, as part of a social or sexual-history discussion.

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

Sexual Orientation

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

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

Gender Identity

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

We strongly support the requirement for gender identity data to be captured in a standardized way in EHRs to support patients' identities, reduce health disparities and facilitate effective clinical risk that may be modified by sexual orientation. However, NACHC proposes the following modification to the gender identity value set based on work from the Gender Identity Working Group at HL7:

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 USCDIv3 submission page does not point to a specific concept for date of death.

Maturity of Use and T	echnical Specifications for Data Element	The applicable standard specified in the draft
Applicable Standard(s) Additional Specifications	Follow the DOB format 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	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
	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.	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.

86345-6	U.S. standard certificate of death - re- revision set	commended 2003	Active	LOINC CODE 80616-6	LONG COMMON NAM Date and time Certificate of	e pronounced dead [US Standard	LOINC STATUS
Term Descr	ption					inde Ad Serrigido - u l	
Contains the s ource: Regenstr	et of terms used in the 2003 version of the U.S. Standard Certificate of Death. Int LOINC			Term Description			
anel Hiera	rchy LOINC in Panel LHC Forms			R1.2.		DC HL7 Version 2.6 Implementation Guide: Reporting De	ath Information from the EHR to Vital Recor
DINC	Name	R/O/C Cardina	lity Example UCUM Units	Source: Regenstrief LOINC			
\$345-6	U.S. standard certificate of death - recommended 2003 revision set		/	Part Description			
69434-9	Location of death name Facility		/	Part Description			
69435-6	Street address where death occurred if not facility			LP203285-4 Date and	time pronounced dead		
74499.5	Death propouncer details			The date and time the	decendent was pronounced dead.		
80616-6	Date and time pronounced dead [US Standard Certificate of Death]		[TmStp]	Source: Centers for Diseas	e Control and Prevention		
31211-6	Date of death						
69454-7	Death date comment			Fully-Specified Na	me		
74497-9	Was the medical examiner or coroner contacted?			Component	Date and time p	ropounced dead	
9453-9	Cause of death [US Standard Certificate of Death]			Property	TmStp		
69440-6	Disease onset to death interval			Time	Pt		
9441-4	Other significant causes or conditions of death	R					
80905-3	Body disposition method			System	^Patient		
59436-4	Were autopsy findings available to complete the cause of death?			Scale	Qn		
69443-0	Did tobacco use contribute to death			Method	US standard cer	tificate of death	
69442-2	Timing of recent pregnancy in relation to death						
69449-7	Manner of death			Basic Attributes			
71481-6	Did the death of this person involve injury of any kind			Dasic Attributes		1	
69445-5	Injury date	C		Class	SURVEY.CDC		
69446-3	Injury date comment	С		Туре	Surveys		
69450-5	Place of injury	c		First Released	Version 2.56		
69444-8	Injury at work?			Last Updated	Version 2.56		
69447-1	Injury location Narrative	c		Order vs. Observatio	n Observation		
11374-6	Injury incident description Narrative	c		L			
69448-9	Injury leading to death associated with transportation event	c					
69451-3	If transportation injury, specify:						
74734-5	Death certifier details				U.S. S	TANDARD CERTIFICATE OF DEATH	
59437-2	Death certifier [Type]						
69439-8	Death certifier Address			ITEMS 24-28 MUST BE CON		24. DATE PRONOUNCED DEAD (Mo/Day/Yr)	25. TIME PRONOUNCE
69452-1	Coroner - medical examiner case number			WHO PRONOUNCES OR CE			
21843-8	History of Usual occupation			26. SIGNATURE OF PERSON PRON	DUNCING DEATH (Only when applical	bie) 27. LICENSE NUMBER	28. DATE SIGNED (Mo/Day/Yr)
21844-6	History of Usual industry			29. ACTUAL OR PRESUMED DATE C	F DEATH 30. AI	CTUAL OR PRESUMED TIME OF DEATH	1. WAS MEDICAL EXAMINER OR
80913-7	Highest level of education [US Standard Certificate of Death]			(Mo/Day/Yr) (Spell Month)	30. A		CORONER CONTACTED? Ses No
69438-0	Forensic medicine Referral note						

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.

Official U	<pre>ffficial URL: http://hl7.org/fhir/us/mdi/StructureDefinition/Observation-death-date ctive as of 2022-03-31</pre>				Version: 1.0.0-ballot			
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7.6.1 Resource Profile: Observation - Death Date

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 Ch	aracter	ristic, Expired"
QDM Datatype⑦	- Devie de coco	
Performance/Reportin QDM Datatype (QDM Ve The "Patient Characteristic Expire	rsion 5.5 Guida	nce Update): Id document that the patient is deceased.
Timing: The "Patient Characterist	ic, 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 Expi	red is fixed to SNOMED	-CT® code 419099009 (Dead) and therefore cannot be further qualified with a value set.
CDC Centers for Dised CDC 24/7: Saving Lives, I		Prevention
Public Health Inform	ation Networl	< Vocabulary Access and Distribution System (PHIN VADS)
		Dead (finding) {419099009, SNOMED-CT }
Code System Concept		Parent/Child (Relationship Type)
Code System Concept Code	419099009	Dead - death without witness (finding) {702710003, SNOMED-CT }
Code System Concept Name	Dead (finding)	Dead - expected (finding) [418646009, SNOMED-CT]
Code System Preferred Concept Na		Dead - sudden death (finding) [418362005, SNOMED-CT]
Concept Status	Published	Dead - suspicious death (finding) {419393000, SNOMED-CT }
Concept Status Date	09/01/2020	Dead - unexpected (finding) {419697005, SNOMED-CT}
Code System Name	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 }
		Found dead (finding) {419973004, SNOMED-CT}

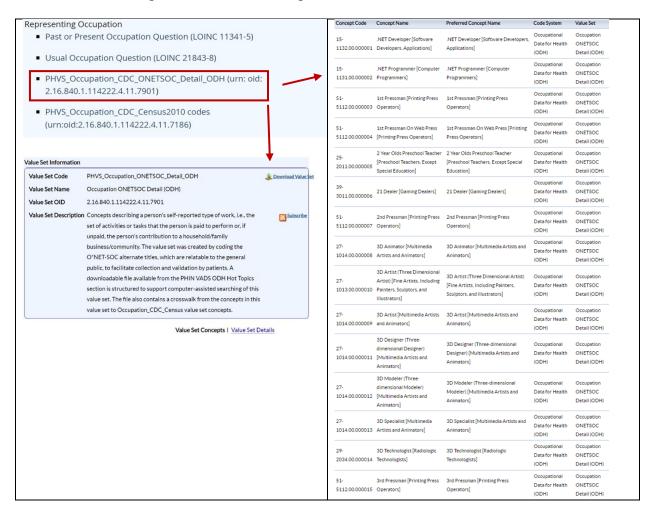
Patient Demographics - Tribal Affiliation

Official URL: http://terminology.hl7.org/ValueS	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 Techn	ical Specifi	cations for Data Element	Code	Display	
· ·			338	Village	of Afognak
Applicable Standard(s)	HL7 FHIR: US Public Health Tribal Affiliation extension HL7 CDA: Tribal Affiliation template		339	Agdaag	ux Tribe of King Cove
		alue Set: TribalEntityUS	340	Native V	/illage of Akhiok
			341	Akiacha	k Native Community
		/www.hl7.org/implement/standards/product_brief.cfm?	342		ative Community
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		//www.hl7.org/implement/standards/product_brief.cfm? ct_id=436 http://terminology.hl7.org/ValueSet/v3-	344		of Alakanuk
		ntityUS	345	Alatna \	
			346		/illage of Aleknagik
Additional Specifications		HL7 FHIR® Implementation Guide: Electronic Case Reporting		1 2 2 2 1 2 2 3 1 2 2 3 1 2 2 3 3 1 2 2 3 3 3 3	native Village (St. Mary's)
		(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	347 348		et Village
			349		/illage of Ambler
	CDA: Tribal Affiliation template	350		of Anaktuvuk Pass	
Current Use	Extens	ively used in production environments	351		f Andreafski
			352		Community Association
Supporting Artifacts	Soon to be published: HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) STU Release 2 Soon to be published: HI 7 CDA® R2 Implementation Guide: Public Health		353	Village	
		hed: HL7 CDA® R2 Implementation Guide: Public Health	354	Anvik V	
	Case F	Case Report - the Electronic Initial Case Report (eICR) Release 1, STU Release 3.0	355		illage (See Native Village of Venetie
	https://www.hl7.org/implement/standards/product_brief.cfm? product_id=519 https://www.hl7.org/implement/standards/product_brief.cfm? product_id=436	356	Asa car Village	sarmiut Tribe (formerly Native of M	
		357	Native V	/illage of Atka	
	produ	LUI0=430	358	Village	of Atmautluak
Number of organizations/individuals with which this data		ore. This data element has been tested at scale between	359	Atqasuk	Village (Atkasook)
element has been electronically exchanged		le different production environments to support the ty of anticipated stakeholders.	360	Native V Gover	/illage of Barrow Inupiat Traditional
			361	Beaver	Village
			362	Native \	/illage of Belkofski
			363	Village	of Bill Moore's Slough
			364	Birch Cr	reek Tribe
			365	Native \	/illage of Brevig Mission
			366	Native V	/illage of Buckland
			367	Native \	/illage of Cantwell
			368	Native \	/illage of Chanega (aka Chenega)
			369	Chalkyit	tsik Village
			370	Village	of Chefornak
			371	Chevak	Native Village
			372	Chickale	oon Native Village

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

Patient Demographics – Occupation and Industry

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



Applicable Security Patterns for Consideration

Representing Industry

- Past or Present Industry Question (LOINC code 86188-0)
- Usual Industry Question (LOINC code 21844-6)
- PHVS_Industry_NAICS_Detail_ODH (urn:oid: 2.16.840.1.114222.4.11.7900)
- PHVS_Industry_CDC_Census2010 codes (urn:oid:2.16.840.1.114222.4.11.7187)

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

Health Insurance Information

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

Health Status – Functional Status

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

Health Status – Disability Status

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

Health Status – Mental Function

NACHC is supportive of the concept of mental function; 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 cognitive function 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. Furthermore, there will likely be confusion between which assessments constitute "Functional Status" and "Mental Function". Would recommend renaming this term. 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 categories of functional status with equivalent semantics and clear terminology bindings.

Health Status – Pregnancy Status | Women's Health

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 SNOMED-CT terminology bindings. The pregnancy status LOINC code that should be referenced is missing or not immediately transparent from the current USCDIv3 draft proposal.

We appreciate the use case for reported pregnancy status in a patient-facing survey; however, for use in electronic health record systems (EHRs), we believe the intended concept should preferentially be the presence of a confirmed pregnancy status referenced by LOINC 82810-3, with its terminology bound answer codes (LOINC LL4129-4). 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 the version 3 draft proposal.

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.

Vital Signs - Average Blood Pressure

	Data Element Name - 1:*		
	Average Blood Pressure		
	Data Element Description:*		
Average Blood Pressure represents the ave specified time period or according to a spec blood pressure is not the same as a mean a has a systolic and a diastolic component.			
	In some scenarios (e.g., self-measured blood p may be used to diagnose hypertension or to ev patients. For this reason, it should be possible t addition to single blood pressure readings.	aluate blood pressure control in hypertensive	
Data Element Name - 2:*		Data Element Name - 3:*	
Average Systolic Blood Pressure		Average Diastolic Blood Pressure	
Data Element Description:*		Data Element Description:*	
A blood pressure average is the average of to specified time period or according to a specific represents the systolic component of an avera-	ed algorithm or protocol. This data element		
specified time period or according to a specified	ed algorithm or protocol. This data element age blood pressure.	specified time period or according to a sp represents the diastolic component of an	ecified algorithm or protocol. This data element
specified time period or according to a specific represents the systolic component of an avera Briefly describe the main use cases to suppo	ed algorithm or protocol. This data element age blood pressure. ort adoption of the data element into e high blood pressure. Average blood	specified time period or according to a sp represents the diastolic component of an Does this data element suppor (check all that apply):*	ecified algorithm or protocol. This data element average blood pressure. t the following aims in healthcare
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specified time period or according to a specific represents the systolic component of an avera Briefly describe the main use cases to suppor the USCDI: Over 120 million adults in the United States have pressure readings can guide the diagnosis and t The 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA Prevention, Detection, Evaluation, and Managen the AHA 2019 Scientific Statement on the Measu provide guidance recommending that to proper • Office-obtained blood pressure measurer	ed algorithm or protocol. This data element age blood pressure. ort adoption of the data element into e high blood pressure. Average blood treatment of hypertension. VASH/ASPC/NMA/PCNA Guideline for the nent of High Blood Pressure in Adults and urement of Blood Pressure in Humans ly estimate an individual's blood pressure: ment should include the average of 2	specified time period or according to a specified time period or according to a specified time period or according to a specified time period. Does this data element support (check all that apply):* X Improving patient experience or X Improving the health of popular	ecified algorithm or protocol. This data element average blood pressure. t the following aims in healthcare of care (quality and/or satisfaction) tions
specified time period or according to a specific represents the systolic component of an avera Briefly describe the main use cases to suppor the USCDI:* Over 120 million adults in the United States have pressure readings can guide the diagnosis and t The 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA Prevention, Detection, Evaluation, and Managem the AHA 2019 Scientific Statement on the Measu provide guidance recommending that to proper	ed algorithm or protocol. This data element age blood pressure. ort adoption of the data element into e high blood pressure. Average blood reatment of hypertension. V/ASH/ASPC/IMMA/PCINA Guideline for the nent of High Blood Pressure in Adults and urement of Blood Pressure in Humans ty estimate an individual's blood pressure: ment should include the average of 2 casions) monitoring, the average of all BP	specified time period of according to a specified time period of according to a specified time period of according to a specified time period. Does this data element support (check all that apply):* X Improving patient experience of X Improving the health of popular X Reducing the cost of care	ecified algorithm or protocol. This data element average blood pressure. t the following aims in healthcare of care (quality and/or satisfaction) tions
specified time period or according to a specific represents the systolic component of an avera Briefly describe the main use cases to suppor the USCDI:* Over 120 million adults in the United States have pressure readings can guide the diagnosis and t The 2017 ACC/AHA/AAPA/ABC/ACPM/ASS/APhA Prevention, Detection, Evaluation, and Managen the AHA 2019 Scientific Statement on the Measu provide guidance recommending that to proper • Office-obtained blood pressure measurem or more BPs obtained on two or more occ • For self-measured blood pressure (SMBF	ed algorithm or protocol. This data element age blood pressure. ort adoption of the data element into treatment of hypertension. VASH/ASPC/NMA/PCNA Guideline for the nent of High Blood Pressure in Adults and arement of Blood Pressure in Humans ity estimate an individual's blood pressure: ment should include the average of 2 casions 2) monitoring, the average of all BP BP readings should be used.	specified time period or according to a specified time period or according to a specified time period. Does this data element support (check all that apply):* X Improving patient experience of X Improving the health of popular X Reducing the cost of care X Improving provider experience	ecified algorithm or protocol. This data element average blood pressure. t the following aims in healthcare of care (quality and/or satisfaction) tions

Laboratory – Specimen Type

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

Laboratory – Result Status

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

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

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

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

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

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

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

Social Determinants of Health have been defined as:

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

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

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

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

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.

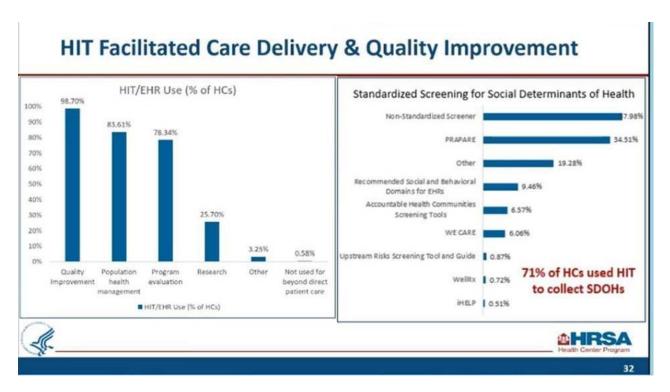


Figure 2 Distribution of EHR use-purpose in FQHCs (Left), distribution of SDOH collection tools (right)

Addressing SDOH in clinical settings:

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

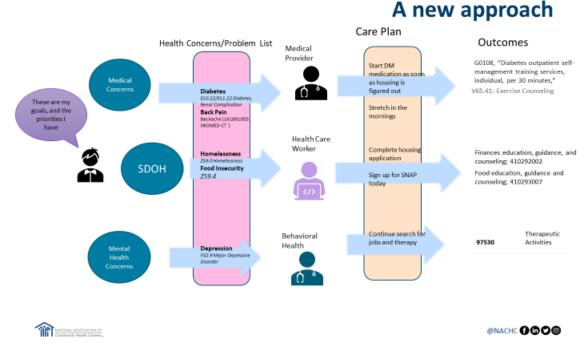


Figure 3 Theoretical framework for addressing ad caring for SDOH data in EHRs via eCare Planning

Social Determinants of Health (SDoH) Assessments

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

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

Social Determinants of Health (SDoH) Goals & Interventions

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

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

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

Ongoing Challenges in FQHCs to Data Exchange using Federal Interoperability Standards

In the past decade, adoption of certified EHRs has gone from limited to nearly universal and community health center EHR use is like that of other ambulatory settings. However, despite the use of these certified HIT systems, there are significant gaps in our ability to effectively capture and extract critical health and administrative data. We think that ONC may not be aware that even where there is required support for elements in the USCDI, that 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 <u>jskapik@nachc.com</u> for any follow up information.

Sincerely,

Jaliaskopik

Julia Skapik, MD, MPH, FAMIA Medical Director, Informatics 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		1. Incarceration History
4. Farmworker Status	13. Social Isolation		•
5. English Proficiency	14. Stress		2. Safety
6. Income	15. Transportation		
7. Insurance			
8. Neighborhood			
9. Housing Status and Stability			

Figure 1 Core and optional set of SDOH collected through PRAPARE

PRAPARE Elements included in ISA

1. Food Insecu	rity
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 Inse	ecurity
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. Transportati	ion 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/

1. Veteran S	tatus
Requirement Level	Must Have
Value set	[PRAPARE] Have you been discharged from the armed forces of the United States?
	\Box Yes \Box No \Box 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?
	\Box Yes \Box No \Box I choose not to answer this question
	Z57 Occupational exposure to risk factors Z57.0 Occupational exposure to noise
	Z57.2 Occupational exposure to dust Z57.3 Occupational exposure to other air contaminants
	Z57.4 Occupational exposure to toxic agents in agriculture
	Z57.6 Occupational exposure to extreme temperature
	Z57.8 Occupational exposure to other risk factors
	Z56.2 Threat of job loss
	Z59.7 Insufficient social insurance and welfare support
	Z60.2 Problems related to living alone
	Z60.3 Acculturation difficulty
	Z60.5 Target of (perceived adverse discrimination and persecution
	Z59.5 Extreme poverty (100% FPL and below)
	Z55.0 Illiteracy and low-level literacy
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?
	\Box English \Box Language other than English (please write): \Box 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 depend on good
	communication between provider and patient. Research has shown that
	adverse events that affect limited English-proficient patients are more likely to
	be caused by communication challenges and are more likely to result in
	serious harm compared to English-speaking patients. (AHRQ, Improving
	Patient Safety Systems for Patients with Limited English Proficiency, 2012)
Use Case	The Use Case for providing essential primary and other clinical care to all
	persons reaching our health care system. This is important for ensuring our
	health care system can deliver quality and patient-centered care as well as for
	both research and public health use cases.
Related Materials	https://www.nachc.org/research-and-data/prapare/

4. Income	
Requirement Level	Must Have
Value set	[PRAPARE] In the past year, what was the total combined income for you and
	the family members you live with? This information will help us determine if
	you are eligible for any benefits.
	\Box Please write: \Box 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/

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5. Insurance	Status
Requirement Level	Must Have
Value set	[PRAPARE] What is your main insurance?
	\Box None/uninsured \Box Medicaid \Box CHIP Medicaid \Box Medicare \Box Other
	public insurance (not CHIP) \Box Other public insurance (CHIP) \Box 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. Neighborł	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?
	\Box Less than high school degree \Box High school degree or GED
	\Box More than high school degree \Box 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 accuration and ability to have
	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. Employme	8. Employment	
Requirement Level	Must Have	
Value set	[PRAPARE] What is your current work situation?	
	\Box Unemployed \Box Part-time or temporary work \Box Full-time work \Box	
	Otherwise unemployed but not seeking work (ex: student, retired, disabled,	
	unpaid primary care giver) Please write: \Box I choose not to answer this question	
	Z56 Problems related to employment/ unemployment	
	Z56.0 Unemployment	
	Z56.1 Change of job	
	Z56.2 Threat of job loss	
	Z56.3 Stressful work schedule	
	Z56.4 Discord with boss and workmates	
	Z56.5 Uncongenial work environment	
	Z56.6 Other physical and mental strain related to work	
	Z56.9 Unspecified problems related to employment	
	Z57 Occupational exposure to risk factors	
	Z59.5 Extreme poverty (100% FPL or below)	
	Z59.6 Low income (200% FPL or below)	
	**See NIOSH code system and MedMorph submission.	

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

9. Material S	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 Isol	ation
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 □ 1 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 Use Case	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. The Use Case for isolation is to understand an individual social support. This
Use Case	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
Requirement Level Value set	Must Have [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 Z56.1 Change of job Z56.2 Threat of job loss Z56.3 Stressful work schedule 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 of adjustment to life-cycle transitions Z60.3 Acculturation difficulty Z60.8 Other problems related to social environment Z60.3 Acculturation difficulty Z60.4 Victim of crime and terrorism Z60.5 Exposure to disaster, war, and other hostilities
	Z59.5 Extreme Poverty (100% FPL or below)
Comments	Z59.6 Low income (200% FPL or below) 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.Incarcerat	tion 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?
	\Box Yes \Box No \Box Unsure \Box 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?
	\Box Yes \Box No \Box Unsure \Box I choose not to answer this question
	In the past year, have you been afraid of your partner or ex-partner?
	\Box Yes \Box No \Box I have not had a partner in the past year \Box 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 S	15.Refugee Status	
Requirement Level	Must Have	
Value set	[PRAPARE] Are you a refugee?	
	\Box Yes \Box No \Box I choose not to answer this question	
Comments	Refugees are at serious risks for being underserved medically. They additionally survey from an amalgamation of other SDOH such as language barriers, housing instability, occupational risk	
Use Case	Health care providers need to be aware of, and sensitive to, cultural diversity, life situations, and other various factors that shape a person's identity to provide safe and quality care to all patients. These factors include refugee status, among other factors. (CDC, Cultural Diversity and Considerations)	
	The Use Case for refugee is to provide competent and sensitive care to this key population. This is important for all aspects care as well as for both research and public health use cases.	
Related Materials	https://www.nachc.org/research-and-data/prapare/	

Appendix B: Sexual Orientation and Gender Identity (SOGI)

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

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

Appendix C: Women's Health – Pregnancy Status

Pregnancy Status Class

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

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

Items:

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

4. Pregnancy S	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 status, postpartum period, and a lactation period if relevant. End date of

Use Case	 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. 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 Detern	nination Method
Requirement Level	Nice to have if EDD used
Value Set	LMP, ultrasound first trimester, ultrasound second trimester, ultrasound third trimester, ultrasound, Ovulation date, Embryo transfer, Other.
Comments	 The determination method is a "Must Have" for both EDD and GA. The method reflects on the accuracy of the resulting date and is critical information to capture. Being able to assess the reliability of the EDD/GA directly impacts clinical management of a pregnant individual; being unable to assess reliability represents a patient safety issue for both the mother and fetus. Value set comments: ACOG recommends the following value set for EDD determination method: LMP Earliest ultrasound date and gestation age in weeks/days First trimester ultrasound Second trimester ultrasound Ultrasound, unknown trimester
	 Ovulation date
	 Embryo transfer date
	 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)	<u>Obstetrics Data Definitions</u> : 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 O	Dutcome
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 loss¹ (loss <20 weeks), stillbirth/fetal death (20 weeks or greater), ectopic/tubal, term birth, preterm birth, unknown, other. Justification: Molar pregnancy should be replaced with Gestational Trophoblastic Disease as the more correct clinical terminology. "Not a live birth" should be removed as other values cover this value. In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss' to reflect these events, and recommends it be added to the value set. "Spontaneous termination <20 weeks gestation" should be removed. Fetal death is widely used and thus ACOG recommends that the value be stillbirth/fetal death to reflect this. The value set should add premature delivery and term birth as both are important to clinical care, research and public health use cases.

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.

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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 <i>fetal death</i> 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 C	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 <i>any</i> "Pregnancy Outcome", not just postpartum status of yes. Not all pregnancies result in a postpartum state, such as an ectopic pregnancy. 	

10. Any pregnar	ncy 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 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). <u>https://loinc.org/91144-6/</u>
	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). <u>https://loinc.org/86645-9/</u>

have alternate to EDD/GA not dependent on pregnant t menstrual period (LMP) should be a "Must Have" and not a "Nice to ve" as a data element. LMP remains important in determining
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D/GA along with the first accurate ultrasound or both. ue set, in addition to date, should include certain, estimated, unknown, A. N/A should have the ability to include the reason for no menses e-menarcheal, hormonal suppression, breastfeeding, hysterectomy, lometrial ablation}.
VITALize: <u>Obstetrics Data Definitions</u> : Estimated Due Date (EDD): e best EDD is determined by last menstrual period if confirmed by early asound or no ultrasound performed, early ultrasound if no known last nstrual period or the ultrasound is not consistent with last menstrual iod, or known date of fertilization (e.g., assisted reproductive nnology). OG Committee Opinion #700 Methods for Estimating the Due Date

2. 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)