

National Association of Community Health Centers 7501 Wisconsin Ave, Suite 1100W Bethesda, MD 20814

April 15, 2021

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 appreciate the value of USCDI in advancing interoperability definitions in addressing our challenges with data capture, extraction, analytics, reuse and workflow. However, we believe the progress in this area must be accelerated to meet critical needs of underserved patients and Federally Qualified Health Centers (FQHCs) who serve as America's health care safety net. We encourage ONC to push HIT developers to improve data standardization and support for data extraction via robust HIT product certification that supports well-defined USCDI data elements in systems deployed for patient care. In support of that aim, this letter describes the health data domains for which we are requesting additional support for interoperability definitions via USCDI. These domains are: Social Determinants of Health, Sexual Orientation, Gender Identity and Sexual Health, Women's Health, Encounters, and COVID-19 related elements.

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 30 million patients annually through 14,000 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 Center Controlled Networks (HCCNs) are groups of health centers working together to use health information technology (health IT) to improve operational and clinical practices. HCCNs help health centers leverage health IT to increase participation in value-based care by enhancing

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the patient and provider experience, advancing interoperability, and using data to enhance value. They provide specialized training and technical assistance to take advantage of economies of scale, including group purchasing power, shared training, and data analytics. Currently, approximately 83% of federally funded health centers participate in an HCCN; increased from approximately 73% over the past 3 years. HCCNs provide support services directly to health centers for the management, integration, and analytics of claims data, clinical data, and social determinants of health data. They also provide support services for the sharing of data through health information exchanges (HIEs) and APIs, as well as support services for data privacy and security. HCCNs have a long and successful track record for improving health center operations. They have developed infrastructures and expertise needed to support their mission driven health center members in improving population health while reducing costs, and while prioritizing patient experience and care team well-being. HCCNs are a critical component to health center interoperability and to the successful, meaningful sharing and utilization of health center patient data. Some HCCNs are also PCAs, serving an entire state's worth of FQHCs.

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 health center patients, we must have electronic clinical tools 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 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 on SDOH, sexual health, women's health and SOGI can inform care delivery, thereby addressing health disparities and empowering providers in achieving health equity. While some have claimed that Health IT has in the past exacerbated health inequities, we believe it has the potential to bridge health disparities by enabling the health care community to better coordinate and integrate value-based, patient-centered care into the EHR workflow.

Social Determinants of Health

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 experiencing a high burden of unmet social and financial needs, and 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 (<u>https://www.nachc.org/prapare</u>)

Core			
UDS SDH Domains	Non-UDS SDH Domains (MU-3)		
1. Race	10. Education		
2. Ethnicity	11. Employment	0	ptional
3. Veteran Status	12. Material Security	1. Incarceration History	3. Domestic Violence
4. Farmworker Status	13. Social Isolation	•	A Defecte a Chattan
5. English Proficiency	14. Stress	2. Safety	4. Refugee Status
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 not always had EHR workflows that support standardized SDOH tools or that consistently use structured terminology to describe 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. In order for FQHCs to consistently evaluate, capture and respond to patients' social needs and to reduce health disparities, NACHC asks ONC to prioritize SDOH data elements described in PRAPARE and listed in Appendix A for inclusion in USCDI v2.

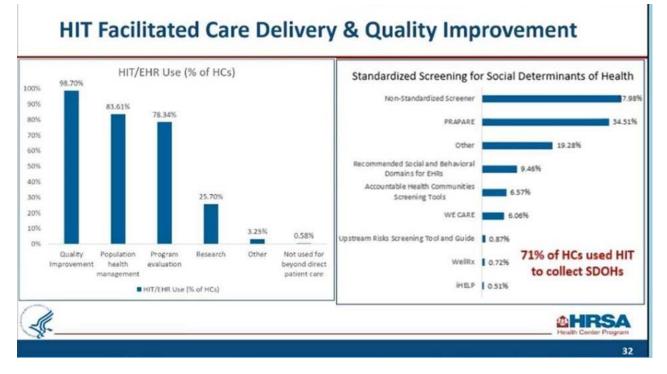


Figure 2 Distribution of EHR use-purpose in FQHCs (Left), distribution of SDOH collection tools (right)

SO/GI

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 and these data elements should be considered critical to promotion 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.

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.
 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. NACHC believes that support for SOGI data elements both validates marginalized communities who experience SOGI-related health disparities and allows health centers to better address their health risks. NACHC asks ONC to prioritize SOGI data elements described in Appendix B for inclusion in USCDI v2.

Addressing SDOH in clinical settings:

In order 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 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. NACHC believes that advancing the concepts of SDOH and SOGI will allow FQHCs to advance standards for electronic care plan, such as FHIR Care Plan, to support interoperable, patient-centered and team-driven approaches to coordinated care.

A new approach

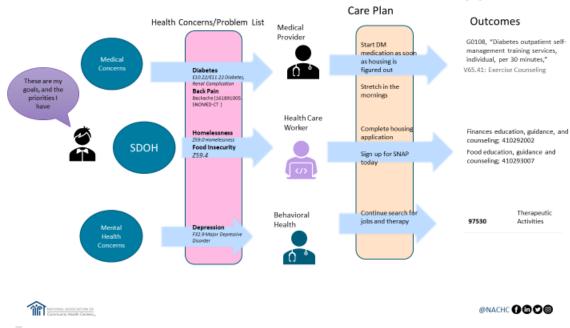


Figure 3 Theoretical framework for addressing ad caring for SDOH data in EHRs via eCare Planning

Sexual Health

Sexually Active

For years there have been metrics and preventive services focused on patients who are at risk because they are sexually active. Many providers routinely ask about sexual history and activity to assess these risks or offer needed services; however, EHRs do not support a standardized data element for sexual activity. As a result, many quality measures and clinical decision support tools use existing sexually related actions to trigger the application, which means many patients at risk are not offered the evidence-based service or included in the CDS or measure because they have yet to experience sequelae of sexual activity. Furthermore, it leads to a huge implementation burden for measure and CDS tools. This is a backwards approach to preventive care which can easily be remedied by the creation of an element for sexual activity that can in turn be used to suggest the provision of relevant services like contraception or HIV screening. **NACHC suggests that ONC add a concept for patients who are sexually active to support sexual and reproductive health care activities.**

Women's Health

Although women make up a majority of the US population and live birth is the most common major procedure in the US, there is not required support for any of the clinical data elements needed to provide safe, high-quality care for women's health and pregnancy in USCDI at this time. The primary use case for many of these elements is for achieving healthy pregnancies and pregnancy-related outcomes including neonatal health as well as maternal. Given the severe health inequities seen in maternal and child outcomes in the US for minorities, standardized and interoperable data which support care coordination and transparent pre-, peri- and post-natal care are critical for addressing these disparities. We have partnered with the American College of Obstetricians and Gynecologists (ACOG) and our maternal and child health providers in FQHCs to develop shared recommendations around women's health.

NACHC since 2018 has been working with the CDC on a project to support post-partum care for women experiencing pregnancy. The support for pregnancy status has been noted to be a major contributor to lack of interoperability and care coordination around post-partum care. Furthermore, many patients experience morbidity and mortality around pregnancy that is likely preventable. The lack of support for women's health data elements is an important contributor to health disparities related to care management and coordination using EHRs around reproductive health. The requirement of pregnancy status in particular could allow health providers to utilize clinical decision support tools and identify patients who require important preventive and high-risk services around pregnancy and birth. To ensure that FQHCs can respond to the maternal and infant mortality crisis in the United States and support women experiencing pregnancy, NACHC asks ONC to prioritize pregnancy status and related women's health concepts for inclusion in USCDI v2.

In 2019, NACHC initiated a project supporting patient-centered contraception counseling and access with the goal of extracting data from certified EHRs as to contraceptive methods. We discovered in this process that women's health implanted devices are exempted from the Promoting Interoperability and USCDI requirements for implanted medical devices. Given that contraceptive implants and intrauterine devices (IUDs) are implanted into the patient's body, we believe that this is an oversight which creates an unjustifiable health inequity for women—they do not have access to the same interoperability for their devices as for devices used by both men and women. Issues around care coordination for patients with these multi-year implanted devices have implications for patient safety and patient's ability to control their decision-making and health information. We ask that ONC immediately remove any exemptions for implanted contraceptive implants and IUDs receive equal treatment to other devices for regulated data capture and exchange in EHRs.

Additional Content

NACHC strongly supports the inclusion of encounters as a data class; support for these elements is critical to understanding utilization of care and the course of a patient's condition. We encourage HHS to consider methods to allow low resource health and social services organizations opportunities to exchange data that do not require expensive licensing agreements.

The COVID-19 pandemic has had a deep impact in FQHCs and their populations. Health centers are often located in areas where economic, geographic, or cultural barriers limit access to affordable health care and serve as a critical safety net for populations at high risk for COVID-19, including racial and ethnic minority groups, migrant and agricultural workers, people experiencing homelessness, residents of public housing and veterans.^{1,2} Furthermore, health centers also serve essential non-health care workers in industry sectors of society (i.e. food processing, manufacturing, construction, health aides) that are at high risk for COVID-19 and disproportionally impacted by the pandemic.^{3,4} Throughout the COVID-19 pandemic, health centers have supported SARS-CoV-2 testing, COVID-19 follow-up care, and vaccination for medically underserved populations, but the data collection and aggregation has been difficult. We encourage ONC to consider adding concepts around COVID-19 and occupational health as described in Appendix E and by the C19 Interoperability Alliance to support the ongoing pandemic and future public health crises.

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; health centers use EHRs at similar rates seen in 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 and many organizations unable to classify lab data accurately due to lack of support for LOINC codes. 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, which is a patient safety risk. Furthermore, in our 2020 COVID-19 data project we have invested hundreds of hours of manual mapping to recategorize all the SARS-CoV-2 lab tests and their result values. These missed opportunities for alignment to ONC requirements result 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 and clarify the system functionality that should be made available across the vendor systems to define data using coded terminologies required in USCDI 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; however, the pace of additions to the data set is too slow to address critical needs and the level of scrutiny of the current certification testing program is not high enough to ensure even the basic functional criteria are met for real world users. We strongly encourage ONC to expand the content added to the USCDIv2 and to develop bidirectional testing of deployed HIT products to guarantee customers have access to the interoperability they need.

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 Health IT. If you have any questions, please contact Julia Skapik at jskapik@nachc.com.

Sincerely,

m yce, m.D.

Ron Yee, MD, MBA Chief Medical Officer

- Jalia Skopik

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

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1. Health Resources and Services Administration. HRSA Health Center Program. 2020. https://bphc.hrsa.gov/sites/default/files/bphc/about/healthcenterfactsheet.pdf.

2. Health Resources and Services Administration. 2019 Uniform Data System--National Health Center Data. 2020. <u>https://data.hrsa.gov/tools/data-reporting/program-data/national</u>.

3. Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine - United States, December 2020. *MMWR Morbidity and mortality weekly report* 2021; **69**(5152): 1657-60.

4. Centers for Disease Control and Prevention. Interim List of Categories of Essential Workers Mapped to Standardized Industry Codes and Titles. 2021. <u>https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html</u>.

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	

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 Insecurity	
Requirement Level	Must Have
Value set	What is your current housing situation? (LOINC® code 71802-3)
	 Answer list (LOINC® code LL5350-5) 1. I have housing 2. I do not have housing (staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, or in a park) 3. I choose not to answer that question
	Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel (LOINC® code 93025-5) Are you worried about losing your housing [PRAPARE] (LOINC® code 93033-9) Z59 Problems related to housing and economic circumstances Z59.0 Homelessness

	Z59.1 Inadequate housing Z59.2 Discord with neighbors, lodgers, and/or landlord Z59.5 Extreme poverty (100% FPL or below) Z59.6 Low income (200% FPL or below)
	Z59.8 Other problems related to housing and economic circumstances
Comments	About 1 in every 17 Americans is homeless, and many more are unstably housed or at risk for eviction
Use Case	The Use Case for housing insecurity is to ensure patients have appropriate shelter, a key element of one's determinants of health. This is important for all aspects of one's care as well as for both research and public health use cases.
Related Materials	https://www.healthit.gov/isa/representing-housing-insecurity
	https://www.nachc.org/research-and-data/prapare/

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

PRAPARE Elements not included in ISA

1. Veteran Status		
Requirement Level	Must Have	
Value set	[PRAPARE] Have you been discharged from the armed forces of the United States?	
	\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. Farmworl	xer 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
	 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)
Comments	Z55.0 Illiteracy and low-level literacy 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 Pr	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. □ 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 supportZ72.4 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) \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. 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	ent
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 □ 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 Uso Coso	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
Requirement Level 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 Z56.5 Uncongenial 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 Z60.0 Problems related to social environment Z60.0 Problems related to social environment 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
Related Materials	cases. 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?
	\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 St	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) and Sexual Health

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 inidviduals receive appropriate care as well as for both research and public health use cases.
Related Materials	https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program- services-report-rsr https://hab.hrsa.gov/program-grants-management/data-reporting-requirements- and-technical-assistance

2. Gender Identity	
Requirement Level	Must Have

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

1. Sexua	1. Sexual Activity	
Requirement	Must Have	
Level		
Value set	SNOMED CT: (Parent code and all children codes in the hierarchy)	
	414254005 - Finding of frequency of sexual activity (finding)	
	162171002 - Currently not sexually active (finding)	
	228453005 - Sexually active (finding)	
	*LOINC	
	64728-9 - Have you ever had vaginal intercourse [PhenX]	
Comments	*eCQM Data Element "Assessment, Performed: Sexually Active" is limited to vaginal intercourse, and does not capture or include sexual activity data elements that are related to sexually transmitted infections secondary to sexual activity aside from vaginal intercourse.	
	Montana's Department of Public Health and Human Services (DPHHS) includes SNOMED CT codes in their "Adolescent Wellness" Registry, addressing the "STI Screening" measure, together with the "Chlamydia Screening in Women" measure.	

Use Case	The Use Case for sexual health is to best identify patients at risk for STIs and unintended pregnancy and to appropriately engage patients in ongoing sexual screening and contraceptive services. This is important for primary and preventive care as well as for both research and public health use cases.
Related Materials	https://ecqi.healthit.gov/mcw/2020/ecqm- dataelement/assessmentperformedsexuallyactive.html
	https://www.ncbi.nlm.nih.gov/medgen/537028 https://dphhs.mt.gov/Portals/85/hrd/documents/MTDAPHRequiredClinicalDataEleme nts20180907.xlsx

Appendix C: Women's Health Data Elements

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. Pregnancy Outcome Date
- 10. Any pregnancy outcome within the last 42 days?
- 11. LMP (Last Menstrual Period)
- 12. <u>Multiplicity of birth/pregnancy</u>

1. Pregnancy S	tatus
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	Must Have
for Method of	
Ascertaining	
Status	
Value set	Patient reported, pregnancy test, urine-based pregnancy test, serum-based
	pregnancy test, ultrasound, clinical impression, history of hysterectomy other.
Comments	NACHC feels that pregnancy status is an important component to understand
	how the status was ascertained and determine how to use the pregnancy status
	data in the record. While these data are available elsewhere, we believe that
	clinical impression should also be clarified to describe a clinical finding or
	exam that confirms the pregnancy as opposed to an impression.

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)	<u>Obstetrics Data Definitions</u> : Estimated Due Date (EDD): The best EDD is determined by last menstrual period if confirmed by early ultrasound or no ultrasound performed, early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or known date of fertilization (e.g., assisted reproductive technology).

4. EDD Determination Method Requirement Level Nice to have if EDD used

Value Set	LMP, ultrasound first trimester, ultrasound second trimester, ultrasound third
	trimester, ultrasound, Ovulation date, Embryo transfer, Other.
Comments	 The determination method is a "Must Have" for both EDD and GA. The method reflects on the accuracy of the resulting date and is critical information to capture. Being able to assess the reliability of the EDD/GA directly impacts clinical management of a pregnant individual; being unable to assess reliability represents a patient safety issue for both the mother and fetus. Value set comments: ACOG recommends the following value set for EDD determination method:
	 LMP Earliest ultrasound date and gestation age in weeks/days First trimester ultrasound Second trimester ultrasound Third trimester ultrasound Ultrasound, unknown trimester Ovulation date Embryo transfer date Intrauterine insemination date Other
ACOG Related Materials	 ACOG Committee Opinion #700 Methods for Estimating the Due Date (05/2017) ACOG Committee Opinion #688 Management of Sub-optimally Dated Pregnancies (03/2017) ACOG Committee Opinion #671 Perinatal Risks Associated with Assisted Reproductive Technology (09/2016)

5. Gestational Age	
Requirement Level	Must Have if Pregnant alternative to EDD
Value Set	Number with units = weeks or days
Comments	Should be weeks AND days, not weeks OR days
ACOG Related Materials (ReVITALize)	<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.

 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: <u>Gynecology Data Definitions</u> 	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
		 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)

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 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). <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>

11. LMP (Last N	Jenstrual 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: <u>Obstetrics Data Definitions</u>: 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)

Appendix D: Encounters

Add Encounters as a required data class

- Terminology bindings: CPT or HCPCS
- Require date, facility and provider metadata
- Require at least one linked Encounter Diagnosis/Condition as represented in ISA

For future promotion:

- Identify and require coded value set definitions for Face-to Face, Telehealth (Audio-only and Video) and Virtual Encounter types as a component of Encounters
- Require Encounter Type (as above) in the metadata for encounters
- Adopt FHIR Encounter profile

Appendix E: COVID-19

Require COVID-19 Status as a specific data element:

- COVID-19 Positive:
- COVID-19 Convalescent:
- COVID-19 Antibody Positive:
- COVID-19 Vaccination Completed:
- COVID-19 Naïve: No history of Positive status, convalescent, antibody positivity or vaccination

Occupational Status: Use NIOSH categories as described by MedMorph submission

Essential Worker: Must support