Common data elements for maternal health research

Eunice Kennedy Shriver Institute of Child Health and Development in Partnership with Johns Hopkins University's Maternal Health Data Innovation & Coordination Hub

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JOHNS HOPKINS UNIVERSITY

Maternal Health Data Innovation & Coordination Hub

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Johns Hopkins University: Elizabeth Stierman, Carrie Wolfson, Amanda Burgess, Sarah Clifford, Meighan Mary, Nicole Cunningham, Dana Sarnak, Sean O'Reilly, Andreea Creanga

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development: Nahida Chakhtoura, Jessica Gleason, Diane Gumina, Caroline Signore

Deloitte Consulting: Areej Haroon, Amanda Holmes, Corinne Hausmann

The members of the two Delphi Working Groups who shared their technical expertise through voting are noted below.

Biomedical Workgroup	
Jyoti Angal	Avera McKennan Research Institute
Khyzer Aziz	Johns Hopkins University
Trisha Bokhoudt	George Washington University
Yvonne Bronner	Morgan State University
Irina Burd	University of Maryland
Nahida Chakhtoura	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Rebecca Clifton	George Washington University
Tara DeYampert	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Anne Dunlop	Emory University
Yasser El-Sayed	Stanford University
Catherine Eppes	Baylor College of Medicine
Alexander Friedman	Columbia University
Kelly Gibson	MetroHealth
Diane Gumina	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Rebecca Hamm	University of Pennsylvania
Karen Plevock Haase	National Heart, Lung, and Blood Institute
Lisa Hollier	Centers for Disease Control
Stephanie Leonard	Stanford University
Monica Longo	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Sherri Longo	Ochsner Health
Deirdre Lyell	Stanford University
Cora MacPherson	George Washington University
Elliott Main	Stanford University

Torri Metz	University of Utah
Erin Michos	Johns Hopkins University
Jessica Olson	Medical College of Wisconsin
Anna Palatnik	Medical College of Wisconsin
Alex Peahl	University of Michigan
Jennifer Peck	University of Oklahoma
Sonja Rasmussen	Johns Hopkins University
Uma Reddy	Columbia University
Meredith Rochon	Society for Maternal-Fetal Medicine
Jeffrey Shaffer	Tulane University
Jeanne Sheffield	Johns Hopkins University
Caroline Signore	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Natasha Williams	New York University
Melissa Wong	National Institutes of Health Office of Research on Women's Health

Psychosocial Workgroup

Gretchen Bandoli	University of California San Diego
Girmay Berhie	Jackson State University
Suzan Carmichael	Stanford University
Arielle Deutsch	Avera McKennan Research Institute
Tara DeYampert	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Julia Dickson-Gomez	Medical College of Wisconsin
Amy Elliott	Avera McKennan Research Institute
Catherine Epps	Baylor College of Medicine
Emily Harville	Tulane University
Natalie Hernandez-Greene	Morehouse School of Medicine
Elizabeth Howell	University of Pennsylvania
Elizabeth Howard	Ochsner Health
Hendree Jones	University of North Carolina
Emily Jones	University of Oklahoma
Michael Kramer	Emory University
Meghan Lane-Fall	University of Pennsylvania
Leah Lipsky	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Allison Mantha	Harvard University
Cristian Meghea	Michigan State University
Sarah Osmundson	Vanderbilt University Medical Center
Susan Perez	The Praxis Project
Diane Putnik	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Mary Shaw	Jackson State University
Elizabeth Sherwin	Stanford University

Karina Shreffler	University of Oklahoma
Caroline Signore	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Alison Steube	University of North Carolina
Mishka Terplan	Friends Institute
Joni Williams	Medical College of Wisconsin
Jing Yu	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development

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For any further information relating to this report, you may contact Dr. Andreea Creanga (email: acreanga@jhu.edu).

Executive Summary

Common data elements (CDEs) are critical for providing consistency in data collection and promoting interoperability and collaboration across research endeavors. Early in 2024, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) convened a panel of experts, with expertise in multiple areas of maternal health research, to advise on the development of CDEs for maternal health research. The CDE development process consisted of four phases: a landscape analysis of CDE repositories, a first Delphi process to prioritize maternal health constructs, a literature review to identify candidate CDEs for prioritized constructs, and a second Delphi process to select CDEs.

In Delphi 1, panelists reviewed a list of 267 biomedical constructs and 194 psychosocial constructs identified during the landscape analysis. Panelists categorized constructs as Tier 1 constructs to be collected by all maternal health researchers, Tier 2 constructs relevant for specific thematic areas of maternal health research or constructs that were not a priority for standardization. 58 constructs (36 biomedical and 22 psychosocial) met criteria for the minimum set of Tier 1 constructs. The literature review identified candidate CDEs for each of the 58 constructs prioritized in Delphi 1. The review team abstracted information on the validity and reliability of CDEs, and any endorsements on the use of these CDEs from professional bodies or federal agencies. In Delphi 2, panelists reviewed a synthesis of the data abstracted from the literature review and then rated the feasibility and validity of specific CDEs.

This report provides the Delphi panel's recommendations for standardized data collection of Tier 1 maternal health research constructs. Recommendations specify standardized questions and response options to capture the minimum required data elements for each Tier 1 construct and offer guidance on data sources, measurement methods, and ethical research considerations.

Introduction

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports research to reduce preventable causes of maternal mortality and severe maternal morbidity and improve health before, during, and after pregnancy. Common data elements (CDEs) are critical for providing consistency in data collection and promoting interoperability and collaboration across these research endeavors.

Early in 2024, NICHD convened a panel of maternal health experts to advise on the development of CDEs for use in maternal health research. The panel included representatives from the IMPROVE Maternal Health Research Centers of Excellence, Maternal-Fetal Medicine Units (MFMU) Network, IMPROVE Maternal Health Community Implementation Program (MH-CIP), American College of Obstetricians and Gynecology (ACOG), Society for Maternal-Fetal Medicine (SMFM), Health Resources and Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), three NIH institutes [NICHD; National Heart, Lung, and Blood Institute (NHLBI); and Social and Behavioral Sciences Branch (SBSB)], and other maternal health experts. These experts formed two working groups to support the development of biomedical and psychosocial CDEs, respectively. The NICHD-funded Maternal Health Data Innovation & Coordination Hub at Johns Hopkins University facilitated these working groups and the CDE-development process.

Approach

The CDE development process consisted of four phases: a landscape analysis of CDE repositories, a first Delphi process to prioritize maternal health constructs, a literature review to identify candidate CDEs for prioritized constructs, and a second Delphi process to select CDEs (Figure 1). Each of the Delphi processes had two rounds of voting to allow iteration. Panelists could make comments and propose additions in the first round; then, after reviewing other panelists' comments, they could revise their responses in the second round.[1] Table 1 provides definitions for key terms (constructs, CDE, and CDE bundle).

Table 1. Key Terms and Definitions

Term	Definition	Example(s)
Construct	A topic of interest, concept, or idea.	Perinatal depression
Common data element (CDE)	"A standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection."[2]	Over the past 2 weeks, how often have you been bothered by feeling tired or having little energy *(Response options: Not at all; Several days; More than half the days; Nearly every day)*
CDE bundle	A grouping of CDEs that are indivisible; they are not considered valid or reliable if not used in their entirety.	Patient Health Questionnaire (PHQ-9) or Edinburgh Postnatal Depression Scale (EPDS)

Figure 1. Common Data Elements Development Process and Timeline

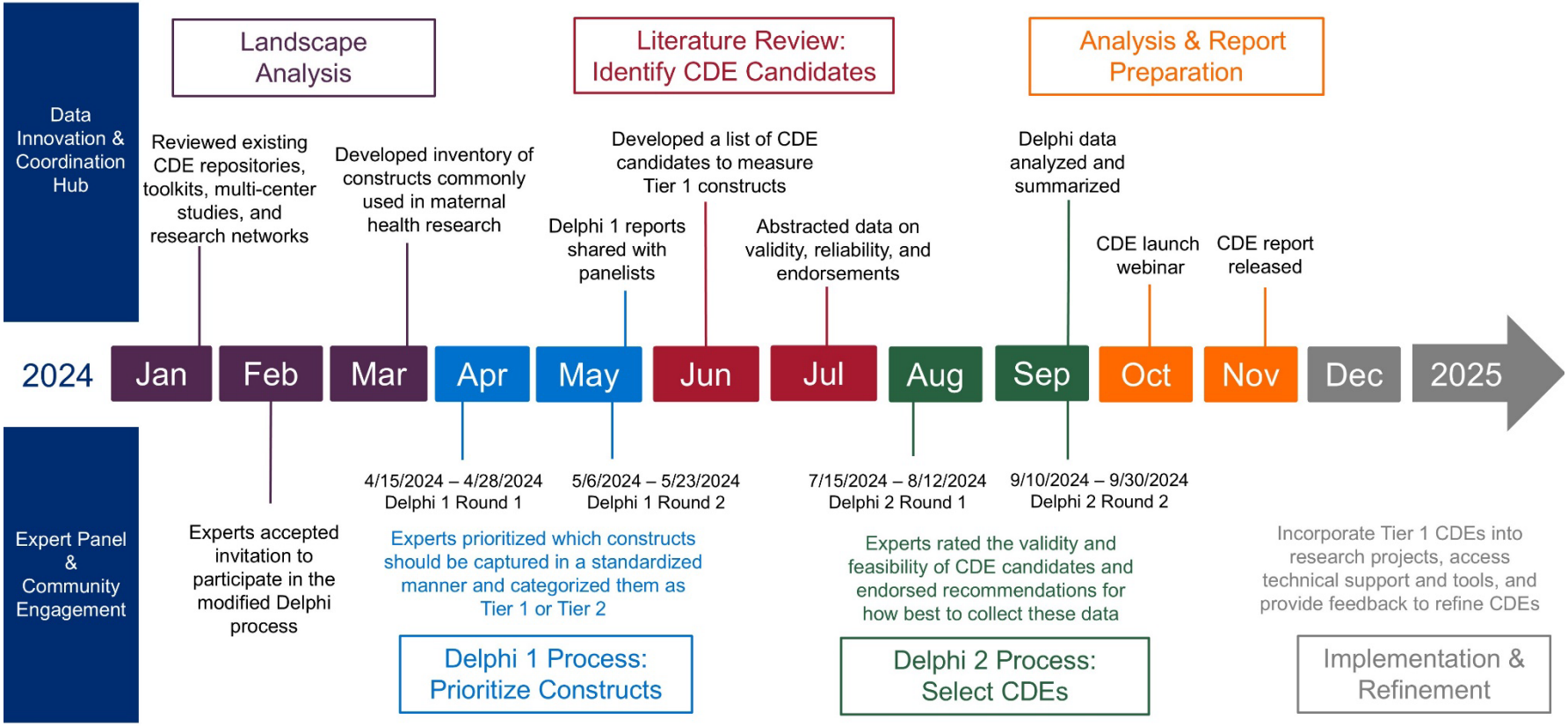

Figure 1: Common Data Elements Development Process and Timeline. January 2024: the Data Innovation & Coordination Hub conducted a landscape analysis. The Hub reviewed existing CDE repositories, toolkits, multi-center studies, and research networks. February 2024: Experts accepted an invitation to participate in the modified Delphi process. March 2024: The Hub developed an inventory of constructs commonly used in maternal health research. April 2024: Round 1 of Delphi 1 was completed. Experts prioritized which constructs should be captured in a standardized manner and categorized them as Tier 1 or Tier 2. May 2024: Round 2 of Delphi 1 was completed, and the Delphi 1 report was shared with panelists. June and July 2024: A literature review identified a list of CDE candidates to measure Tier 1 constructs. Data on validity, reliability, and endorsements were abstracted. August 2024: Round 1 of Delphi 2 was completed. Experts rated the validity and feasibility of CDE candidates and endorsed recommendations for how best to collect these data. September 2024: Round 2 of Delphi 2 was completed. Delphi data were analyzed and summarized. October 2024: A webinar was held for the CDE launch. November 2024: The CDE report was released. December 2024 and continuing to 2025: CDEs entered the implementation and refinement phase. Research Centers of Excellence will incorporate Tier 1 CDEs into research projects, access technical support and tools, and provide feedback to refine CDEs.

Landscape Analysis
In the first phase, a landscape analysis was conducted to identify constructs commonly used in maternal health research and ascertain how these constructs are measured. This included a review of CDE repositories and data collection plans and instruments developed by research networks (Table 2). Data were abstracted from these sources to develop an inventory of maternal health research constructs.

Table 2. Data Sources Reviewed for Landscape Analysis

Name	Description
CDE Repository	
PhenX Toolkit[3-4]	Web-based catalog of recommended measurement protocols of phenotypes and exposures suitable for genomic, clinical, and translational research studies with human participants.
HealthMeasures[5]	Repository consists of PROMIS[6], Neuro-QoL[7], ASCQ-Me[8], and NIH Toolbox[9]. These precise, flexible, and comprehensive measurement systems assess physical, mental, and social health; symptoms; well-being and life satisfaction; along with sensory, motor, and cognitive function.
Disaster Research Response (DR2) Resource Portal[10]	Repository of data collection tools and related resources curated by the DR2 Program to empower human health research in response to disasters and public health emergencies. It hosts the recommended CDEs for COVID-19 Pregnancy Research.
NIH Common Data Element Repository[2]	Repository provides access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH Institutes and Centers for use in research and for other purposes.
United States Core Data for Interoperability+ (USCDI+)	Standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. This includes “USCDI core data”[11] and additional USCDI+ data for domains such as maternal health[12], public health[13], and healthcare quality[14].
Research Networks	
IMPROVE Maternal Health Research Centers of Excellence[15]	Funded by NICHD, the IMPROVE Maternal Health Research Centers of Excellence design and conduct research projects to address the biological, behavioral, environmental, socio-cultural, and structural factors that affect pregnancy-related complications and deaths.
Stillbirth Collaborative Research Network[16]	Funded by NICHD, the Stillbirth Collaborative Research Network was established to study the scope and causes of stillbirths in the United States. Multiple clinical sites participate in a population-based cohort and conduct nested case-control studies.
Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMOM2b)[17]	Funded by NHLBI and NICHD, nuMOM2b followed participants through a series of studies to better understand how pregnancy problems are linked to future heart health.
MATernaL and Infant NetworK to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy (MAT-LINK)[18]	CDC’s MAT-LINK project created a data platform and standard maternal and infant data elements to collect linked maternal and infant data among women treated for opioid use disorders during pregnancy.

Study of Pregnancy and Neonatal Health (SPAN)[19]	Funded by NICHD, SPAN is a multi-site study investigating how different factors in pregnancy affect children's fetal growth and birth outcomes.
Pregnancy Risk Assessment and Monitoring System (PRAMS)[20]	PRAMS is a joint surveillance project between state, territorial, or local health departments and CDC's Division of Reproductive Health. PRAMS is designed to identify groups of women and infants at high risk for health problems to monitor changes in health status and to measure progress towards goals in improving the health of mothers and infants.
All of Us[21]	Funded by NIH, the All of Us research program collects and analyzes data from over 1 million people living in the United States aiming to accelerate health research and medical breakthroughs and to enable individualized prevention, treatment, and care.
Multiple Chronic Diseases Disparities Research Consortium[22]	Funded by the National Institute on Minority Health and Health Disparities, this national consortium of health researchers and community partners brings innovative solutions for prevention and management of multiple chronic conditions.
Gravity Project[23]	The Gravity Project is a national public collaborative that develops consensus-based data standards to improve how we use and share information on social determinants of health.
Clinical quality measures from professional associations and federal agencies	Sources included the Alliance for Innovation on Maternal Health (AIM)[24], Centers for Medicare and Medicaid Services (CMS)[25], Core Quality Measures Collaborative (CQMC)[26], Joint Commission[27], Leapfrog[28], National Quality Forum[29-30], and Society for Maternal-Fetal Medicine (SMFM)[31].

Delphi 1 Process: Prioritization of Constructs

Delphi 1 prioritized *which constructs* should be captured in a standardized manner across maternal health research. Panelists voted on the list of constructs identified during the landscape analysis and categorized them as Tier 1, Tier 2, or not a priority for standardization (Figure 2). Tier 1 constructs were to be collected by all maternal health researchers and researchers enrolling study participants who are pregnant or postpartum. Tier 2 constructs were relevant for specific thematic areas of maternal health research. Panelists considered the importance of standardized data collection for each construct when voting, including its value in advancing maternal health research collaboration and enabling interoperability of data across multiple research projects.

Figure 2. Definitions of Tier 1 and Tier 2 Constructs

Tier 1 constructs

All Maternal Health Studies

Tier 1 constructs are to be collected by all maternal health researchers and researchers enrolling study participants who are pregnant or postpartum.

Tier 2 constructs

Some Maternal Health Studies

Tier 2 constructs are defined as constructs relevant for specific thematic areas of maternal health research (e.g. perinatal mental health).

Two voting rounds were conducted to build consensus on prioritization. During the first round, panelists could propose “write-in” constructs to be voted on during the second round. After the first round, each panelist received an individualized report detailing the distribution of all responses, their own responses, and whether consensus was achieved on a particular construct. During the second round, panelists could revise their responses. After both rounds of voting, constructs for which >80% of panelists affirmed the importance of standardization (either Tier 1 or Tier 2) were retained. Among these, constructs receiving >75% Tier 1 votes were included in the minimum set of Tier 1 constructs; the remainder were classified as Tier 2.

Literature Review

In preparation for Delphi 2, a list of CDE candidates was compiled for each construct prioritized in Delphi 1. CDEs were identified through literature searches and a review of the repositories, toolkits, and multi-center studies cited in the landscape analysis (Table 2). From these sources, information was abstracted on the validity and reliability of CDE candidates, as well as any endorsements or recommendations on their use from professional organizations or federal agencies. Constructs were grouped into two categories based on evidence synthesized from the literature review. The first category included constructs for which there already existed an emerging consensus among researchers, professional groups, and government agencies on best practices for standardized data collection. The second category included constructs where multiple, valid options existed for measuring the construct.

Delphi 2 Process: Selection of CDEs

Delphi 2 recommended *how to measure* the constructs prioritized in Delphi 1, including the selection of specific CDEs or CDE bundles, recommended data sources, and measurement guidance. For constructs where consensus existed on best practices for standardized data collection, panelists voted on whether to endorse the consensus recommendations. For constructs where multiple measurement options existed, panelists rated the validity and feasibility of each CDE candidate using a 5-point Likert scale based on the following feasibility and validity considerations:

- Feasibility considerations. The CDE can be: a) measured with available data of acceptable quality; b) obtained with reasonable and affordable efforts in a timely manner; c) does not overly increase the reporting burden. Feasibility also considered whether the CDE is proprietary, as this may have implications for access and affordability.
- Validity considerations. The CDE: a) measures what it is supposed to measure; b) has been field-tested and used in research; c) makes sense logically and scientifically.

Delphi 2 included two voting rounds to build consensus. Panelists could propose “write-in” CDEs during the first round, which others voted on during the second round. The process also included opportunities for panelists to comment on the validity of data sources and other scientific and ethical considerations related to measurement of the construct. These comments were reviewed and integrated into detailed measurement guidance for each CDE.

Results

Landscape Analysis

The landscape analysis identified 461 constructs commonly used in maternal health research. This included 267 constructs categorized into 11 biomedical domains and 194 constructs categorized into 13 psychosocial domains (Figure 3).

Figure 3. Summary of the Prioritization of Constructs

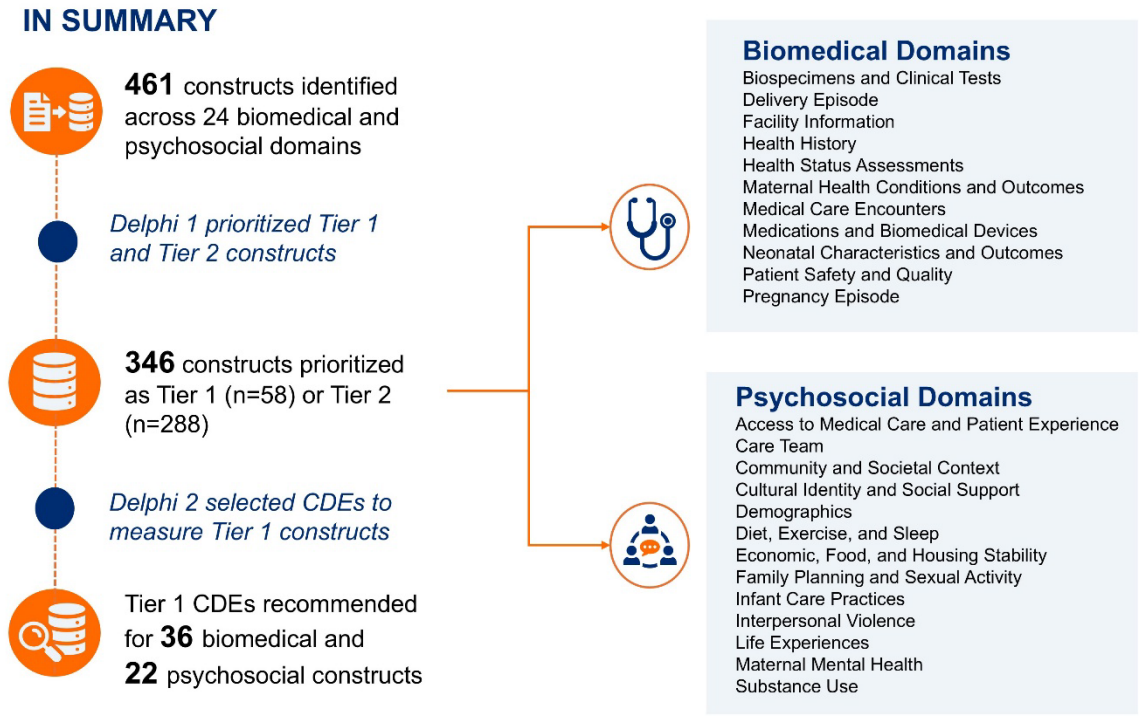

Figure 3: Summary of the Prioritization of Constructs. In the first step, 461 constructs were identified across 24 biomedical and psychosocial domains. Biomedical domains included biospecimens and clinical tests; the delivery episode; facility information; health history; health status assessments; maternal health conditions and outcomes; medical care encounters; medications and biomedical devices; neonatal characteristics and outcomes; patient safety and quality; and the pregnancy episode. Psychosocial domains included access to medical care and patient experience; care team; community and societal context; cultural identity and social support; demographics; diet, exercise, and sleep; economic, food, and housing stability; family planning and sexual activity; infant care practices; interpersonal violence; life experiences; maternal mental health; and substance use. Delphi 1 prioritized Tier 1 and Tier 2 constructs. 346 constructs were prioritized as Tier 1 or Tier 2. Of these, 58 were Tier 1, and 288 were Tier 2. Delphi 2 selected CDEs to measure Tier 1 constructs. Tier 1 CDEs were recommended for 36 biomedical and 22 psychosocial constructs.

Delphi 1 Process: Prioritization of Constructs

During Delphi 1, panelists voted on the 461 constructs (267 biomedical and 194 psychosocial) identified during the landscape analysis. Table 3 shows characteristics of experts participating in the Delphi panel. Participation was high with response rates above 80% for both voting rounds:

- 31 of 37 (84%) members of the Biomedical Working Group participated in the first round of voting, and 30 of 37 (81%) participated in the second, validation round.
- 25 of 30 (83%) members of the Psychosocial Working Group participated in the first round of voting, and 26 of 30 (87%) participated in the second, validation round.

Table 3. Characteristics of the Delphi Expert Panelists

	Biomedical Working Group (N=31)	Psychosocial Working Group (N=25)
Characteristics	n (%)	n (%)
Primary Role	***N=29***	***N=24***
Clinical / health care provider	12 (41%)	2 (9%)
Research	17 (59%)	22 (91%)
Years of Experience	***N=28***	***N=20***
0-10 years	4 (14%)	7 (35%)
11-20 years	10 (36%)	9 (45%)
21+ years	14 (50%)	4 (20%)
Research Experience*	***N=28***	***N=22***
Clinical maternal healthcare	24	10
Health disparities	11	17
Health systems and policy	10	9
Social determinants of health	10	19
Patient safety and quality	10	4
Clinical reproductive healthcare	8	3
Clinical neonatal healthcare	7	6
Substance use	6	12
Indigenous health	3	4
Mental health	3	8

*Note: *Many panelists have research experience in one or more of the areas noted above.*

Among the 461 constructs considered, 115 constructs (65 biomedical and 50 psychosocial) did not meet the threshold for prioritization, with <80% yes votes, and were removed from the list. The remaining 346 constructs (202 biomedical and 144 psychosocial) reached the initial threshold with >80% of panelists affirming the importance of standardization (i.e., a yes vote for either tier).

The list was further restricted to a minimum set of Tier 1 constructs (Table 4). To meet *minimum set* criteria, the construct must have had >80% yes votes for either tier and >75% Tier 1 votes. For example, a construct with 85% yes responses (77% Tier 1 + 8% Tier 2) would meet criteria. A construct with 78% yes responses (76% Tier 1 + 2% Tier 2) votes would not meet criteria. 58 constructs (36 biomedical and 22 psychosocial) met the criteria for the minimum set of Tier 1 constructs. The remaining 288 prioritized constructs (166 biomedical and 122 psychosocial) were classified as Tier 2.

Table 4. Minimum Set of Tier 1 Constructs

Biomedical Tier 1	Psychosocial Tier 1
Pregnancy / Delivery Episode • Pregnancy / postpartum status • Gestational age and estimated due date • Date of delivery / end of pregnancy • Days postpartum at time of event • Plurality • Pregnancy outcome • Mode of delivery **Maternal Health Conditions and Outcomes** • Cardiovascular conditions • Gestational diabetes • Hypertensive disorders of pregnancy • Obstetric hemorrhage • Placental disorders and complications • Sepsis • Severe maternal morbidity • Death during pregnancy / postpartum • Cause(s) of death during pregnancy / postpartum • Date of death during pregnancy / postpartum **Neonatal Characteristics and Outcomes** • Date of birth • Neonatal birth weight • Sex of neonate • Neonatal death • Cause(s) of neonatal death • Date of neonatal death • Fetal death • Cause(s) of fetal death • Timing of fetal death **Health Status Assessments** • Height • Pre-pregnancy weight • Weight (current) • Gestational weight gain **Health History** • Pregnancy history • Prior cesarean • Chronic (pre-gestational) diabetes • Comorbidities **Medical Care Encounters** • Maternal ICU admission • NICU admission or step-up care	**Maternal Mental Health** • Depressive disorders **Substance Use** • Alcohol use • Smoking / tobacco use • Substance / drug use **Interpersonal Violence** • Intimate partner violence **Infant Care and Feeding Practices** • Human milk / breastfeeding initiation and duration **Access to Medical Care** • Health insurance coverage and coverage changes • Access to maternity care **Economic and Food Security** • Financial strain / material hardship • Food security • Transportation insecurity **Life Experiences** • Life experiences **Maternal Demographics** • Current age • Race and ethnicity • Sex • Disability status • Educational attainment • Partnership / marital status • Primary language • Family income • Current place of residence • Birthplace

Literature Review
The literature review identified 89 biomedical and 115 psychosocial CDEs or CDE bundles relevant for the measurement of the minimum set of Tier 1 constructs. Data on validity and reliability of each of the constructs was abstracted from peer-reviewed sources and summarized in tables. Information on whether CDEs had been endorsed or recommended by government agencies, expert panels, or professional associations was abstracted from official reports and websites.

Delphi 2 Process: Selection of CDEs
During Delphi 2, panelists voted on CDE recommendations for the measurement of the Tier 1 constructs. Response rates were 70% or higher for both voting rounds:

- 30 of 37 (81%) members of the Biomedical Working Group participated in the first round of voting, and 29 of 37 (78%) participated in the second, validation round.
- 21 of 30 (70%) members of the Psychosocial Working Group participated in the first round of voting, and 21 of 30 (70%) participated in the second, validation round.

Recommendations emerging from this iterative process are presented in the next section of this report and the annex. These reflect the panel's endorsement of specific CDEs or CDE bundles, recommended data sources, and other measurement guidance.

Recommendations

Tables 5-6 summarize the Delphi panel's recommendations for standardized data collection of Tier 1 maternal health research constructs. The annex provides detailed recommendations for each biomedical and psychosocial construct in narrative format. These recommendations specify standardized questions and response options to capture the minimum data elements for each Tier 1 construct and offer guidance on data sources, measurement methods, and research ethics considerations.

Table 5. Recommendations for Biomedical Common Data Elements

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Pregnancy / postpartum status	Are you pregnant now?	Yes / No / Don't Know	Self-report	• PhenX Toolkit. Current Pregnancy Status - Self-Report. https://www.phenxtoolkit.org/protocols/view/240603
	Have you been pregnant in the past 12 months?	Yes / No	Self-report	• Adapted from AIM Pregnancy Screening Statement. https://saferbirth.org/aim-pregnancy-screening-statement/
	Pregnancy test result	Positive / Negative / Invalid	Bioassay	• PhenX Toolkit. Current Pregnancy Status - Bioassay. https://www.phenxtoolkit.org/protocols/view/240601
Gestational age and estimated due date	Gestational age: number of completed weeks	Numeric	Recommended: EHR, Vital records	• PhenX Toolkit. Gestational Age - Medical Record Abstraction. https://www.phenxtoolkit.org/protocols/view/240902 • U.S. Standard Certificate of Live Birth. • PhenX Toolkit. Gestational Age - Maternal Interview. https://www.phenxtoolkit.org/protocols/view/240901
	Estimated due date	Year, month, day	Alternative: Self-report	
Date of delivery / end of pregnancy	Date of delivery / end of pregnancy	Year, month, day	EHR, Vital records, Hospital discharge / claims data, Self-report	• U.S. Standard Certificate of Live Birth. • Canelón SP, et al.
Days postpartum at time of event	Number of days since date of delivery / end of pregnancy	Numeric	EHR, Vital records, Hospital discharge / claims data, Self-report	• Canelón SP, et al.
Plurality	Number of fetuses delivered live or dead at any time in the pregnancy	Numeric	EHR, Vital records, Hospital discharge / claims data, Self-report	• National Center for Health Statistics. Plurality. • LOINC, 57722-1: https://loinc.org/57722-1
Pregnancy outcome	Was the pregnancy a live birth, stillbirth, miscarriage, abortion, or ectopic pregnancy?	• Live birth • Stillbirth (>=20 weeks) • Miscarriage / spontaneous abortion (<20 weeks) • Abortion (induced) • Ectopic pregnancy • Prefer not to answer	EHR, Self-report	• Adapted from PhenX Toolkit. Reproductive History - Female. https://www.phenxtoolkit.org/protocols/view/101301

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Mode of delivery	Mode of delivery	• Spontaneous vaginal • Forceps vaginal • Vacuum vaginal • Cesarean delivery • Other (specify, e.g., breech extraction)	Recommended: EHR, Vital records, Hospital discharge / claims data Alternative: Self-report	• PhenX Toolkit. Mode of Delivery - Medical Record Abstraction. https://www.phenxtoolkit.org/protocols/view/241302 • World Health Organization. ICD-10. https://icd.who.int/browse10/2016/en#/O80-O84 • American Medical Association. Current Procedural Terminology Codes. https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2022-chapter-7.pdf • U.S. Standard Certificate of Live Birth. • PhenX Toolkit. Mode of Delivery - Interview. https://www.phenxtoolkit.org/protocols/view/241301
Cardiovascular conditions	Congenital heart disease	Yes / No	EHR, Hospital discharge / claims data	• AIM. Cardiac Conditions in Obstetric Care Patient Safety Bundle, Core Data Collection Plan, v1.1. 2024.
	Cardiac valve disorders	Yes / No		
	Cardiomyopathies	Yes / No		
	Arrhythmias	Yes / No		
	Coronary artery disease	Yes / No		
	Pulmonary hypertension	Yes / No		
	Other/not specified	Yes / No		
Gestational diabetes	Gestational diabetes	Yes / No	Recommended: Laboratory, EHR, Hospital discharge / claims data Alternative: Self-report	• PhenX protocol - gestational diabetes. https://www.phenxtoolkit.org/protocols/view/241001 • World Health Organization. ICD-10. https://icd.who.int/browse10/2019/en#/O24 • PRAMS: https://www.cdc.gov/prams/about/index.html
Hypertensive disorders of pregnancy	Chronic hypertension	Yes / No	Recommended: EHR, Hospital discharge / claims data Alternative: Self-report	• AIM. Severe Hypertension in Pregnancy Patient Safety Bundle, Core Data Collection Plan, v2.0. 2024. • PRAMS: https://www.cdc.gov/prams/about/index.html
	Gestational hypertension	Yes / No		
	Preeclampsia	Yes / No		
	Eclampsia	Yes / No		
	HELLP Syndrome	Yes / No		
Obstetric hemorrhage	Antepartum hemorrhage	Yes / No	EHR, Hospital discharge / claims data	• AIM. Obstetric Hemorrhage Patient Safety Bundle, Core Data Collection Plan, v2.0. 2024. • Lagrew D, et al. Improving Health Care Response to Obstetric Hemorrhage, a California Maternal Quality

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
	Postpartum hemorrhage	Yes / No		Care Collaborative Toolkit, 2022 pp.174-183 • Clapp MA, et al.
Placental disorders and complications	Placenta previa Placental abruption Placenta accreta spectrum	Yes / No Yes / No Yes / No	EHR, Ultrasound	• ACOG-SMFM Obstetric Care Consensus: Placenta Accreta Spectrum, Vol.136, No. 6, 2018 • ACOG: https://www.acog.org/womens-health/dictionary
Sepsis	Sepsis	Yes / No	EHR, Hospital discharge / claims data	• AIM. Sepsis in Obstetric Care Patient Safety Bundle, Core Data Collection Plan, v1.1. 2024.
Severe maternal morbidity	SMM event occurred Criteria used to identify the occurrence of SMM event Applicable ICD code (if CDC criteria used) Applicable category (if ACOG-SMFM criteria used)	Yes / No • CDC • ACOG-SMFM Specify applicable ICD-10 code (see "mapping / source" column for list of codes) • Admission to an ICU • Transfusion of 4 or more units of blood	EHR, Hospital discharge / claims data	• ACOG-SMFM: https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2016/09/severe-maternal-morbidity-screening-and-review • CDC: https://www.cdc.gov/maternal-infant-health/php/severe-maternal-morbidity/icd.html
Death during pregnancy / postpartum	Death occurred	Yes / No	Recommended: Vital records Alternative: EHR	• U.S. Standard Certificate of Death.
Cause of death during pregnancy / postpartum	Criteria used to classify cause of death Cause of death	• PMSS-MM • ICD-10 Specify applicable PMSS-MM or ICD-10 code (see "mapping / source" column for list of codes)	Recommended: Triangulation across multiple data sources Alternative: A single data source, such as Vital records, EHR, or Autopsy reports	• PMSS-MM codes: https://www.cdc.gov/maternal-mortality/media/pdfs/2024/05/mmria-form-v24-fillable-508.pdf • ICD-10 codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593
Date of death during pregnancy / postpartum	Date of death	Year, month, day	Recommended: Vital records Alternative: EHR, Hospital discharge / claims data, Proxy-report by family member	• U.S. Standard Certificate of Death.

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Date of birth	Date of birth	Year, month, day	Recommended: Vital records Alternative: EHR, Hospital discharge / claims data, Proxy-report by parent or caregiver	• U.S. Standard Certificate of Live Birth.
Neonatal birth weight	Number of grams	Numeric	Recommended: Vital records, EHR, Physical examination Alternative: Proxy-report by parent or caregiver	• PhenX Toolkit. Birth Weight - Birth Weight Abstracted from Medical Records. https://www.phenxtoolkit.org/protocols/view/20201 • PhenX Toolkit. Birth Weight - Measured Weight at Birth. https://www.phenxtoolkit.org/protocols/view/20202 • U.S. Standard Certificate of Live Birth. • PhenX Toolkit. Birth Weight - Proxy Reported Birth Weight. https://www.phenxtoolkit.org/protocols/view/20203
Sex of neonate	Sex of neonate	• Male • Female • Sex not yet determined	Vital records, EHR, Hospital discharge or claims data, Proxy-report by parent or caregiver	• U.S. Standard Certificate of Live Birth.
Neonatal death	Neonatal death occurred	Yes / No	Recommended: Vital records Alternative: EHR	• U.S. Standard Certificate of Death.
Cause(s) of neonatal death	Criteria used to classify cause of neonatal death Cause(s) of neonatal death	• FIMR • ICD-10 code Specify applicable FIMR or ICD-10 code (see "mapping / source" column for list of codes)	Recommended: Triangulation across multiple data sources Alternative: A single data source, such as Vital records, EHR, or Autopsy reports	• FIMR codes: https://ncfrp.org/wp-content/uploads/DataDictionary_CRS_v6-0.pdf (G6; pages 61-62) • ICD-10 codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593
Date of neonatal death	Date of neonatal death	Year, month, day	Recommended: Vital records Alternative: EHR, Hospital discharge / claims data, Proxy-report by family member	• U.S. Standard Certificate of Death.
Fetal death	Fetal death occurred	Yes / No	Vital records	• Model State Vital Statistics Act and Regulations. • U.S. Standard Report of Fetal Death.

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Cause(s) of fetal death	Criteria used to classify cause of fetal death Cause(s) of fetal death	• SCRN • FIMR • ICD-10 code Specify applicable SCRN or FIMR or ICD-10 code (see "mapping / source" column for list of codes)	Recommended: Triangulation across multiple data sources Alternative: Vital statistics data after review by state or federal statistics program	• SCRN: https://links.lww.com/AOG/A186 • FIMR (pp. 61-62): https://ncfrp.org/wp-content/uploads/DataDictionary_CRS_v6-0.pdf • ICD-10 codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593
Timing of fetal death	Timing of fetal death	• Dead at time of first assessment, no labor ongoing; • Dead at time of first assessment, labor ongoing; • Died during labor, after first assessment; and • Unknown time of fetal death.	Recommended: Vital records Alternative: EHR, Proxy-report by family member	• U.S. Standard Report of Fetal Death.
Height [maternal]	Number of centimeters	Numeric	Recommended: Physical examination, EHR Alternative: Vital records, Self-report	• PhenX Toolkit. Height - Standing Height. https://www.phenxtoolkit.org/protocols/view/20706 • U.S. Standard Certificate of Live Birth. • PhenX Toolkit. Height - Self-Reported Height. https://www.phenxtoolkit.org/protocols/view/20707
Pre-pregnancy weight	Number of kilograms	Numeric	Recommended: EHR Alternative: Self-report	• PhenX Toolkit. Total Pregnancy Weight Gain - Self-Reported Weight Gain. https://www.phenxtoolkit.org/protocols/view/21301
Weight (current)	Number of kilograms	Numeric	Physical examination, EHR	• PhenX Toolkit. Weight - Measured Weight. https://www.phenxtoolkit.org/protocols/view/21503
Gestational weight gain	Number of kilograms	Numeric	Recommended: Physical examination, EHR Alternative: Self-report	• PhenX Toolkit. Total Pregnancy Weight Gain - Weight Measured During Gestation. https://www.phenxtoolkit.org/protocols/view/21303 • PhenX Toolkit. Total Pregnancy Weight Gain - Abstracted from Prenatal Charts. https://www.phenxtoolkit.org/protocols/view/21302 • PhenX Toolkit. Total Pregnancy Weight Gain - Self-Reported Weight Gain. https://www.phenxtoolkit.org/protocols/view/21301
Pregnancy history	Gravidity	Numeric	Recommended: EHR	

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
	Parity Abortus Duration of previous pregnancies	Numeric Numeric Number of weeks	Alternative: Self-report	• Callahan A, et al. • PhenX Toolkit. Reproductive History - Female. https://www.phenxtoolkit.org/protocols/view/101301
Prior cesarean delivery	Prior cesarean delivery	Yes / No	Hospital discharge / claims data, EHR, self-report	• ICD-10 codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=0CD1BE9C-1351-452E-A904-50441CB98B16 • ATHENA: https://athena.ohdsi.org/search-terms/terms?query=repeat+cesarean • PhenX Toolkit. Mode of Delivery - Interview. https://www.phenxtoolkit.org/protocols/view/241301
Chronic (pre-gestational) diabetes	Chronic (pre-gestational) diabetes	Yes / No	Recommended: Hospital discharge / claims data, EHR Alternative: Self-report	• ATHENA: https://athena.ohdsi.org/search-terms/terms/201820 • ATHENA: https://athena.ohdsi.org/search-terms/terms?conceptClass=ICD10+code&page=1&pageSize=15&query=diabetes+mellitus&boosts • PRAMS: https://www.cdc.gov/prams/about/index.html
Comorbidities	Obstetric comorbidity score	Numeric	Hospital discharge / claims data, EHR	• Leonard SA, et al.
Maternal ICU admission	Maternal ICU admission	Yes / No	Hospital discharge / claims data, EHR	• ACOG-SMFM: https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2016/09/severe-maternal-morbidity-screening-and-review • ICU Revenue Center Code: https://resdac.org/cms-data/variables/intensive-care-unit-icu-indicator-code
NICU admission / step-up care	Highest level of medical care provided to infant	• Well newborn nursery • Special care nursery • Admission to NICU • Admission to regional NICU	Recommended: EHR Alternative: Hospital discharge / claims data	• Joint Commission: https://manual.jointcommission.org/releases/TJC2018A/DataElem0275.html • Revenue Center Codes: https://www.aha.org/system/files/media/file/2020/01/RC%2017x.pdf

Table 6. Recommendations for Psychosocial Common Data Elements

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Depressive disorders	Presence of depressive symptoms	Yes (score ≥ 10) / No (score <10)	Self-report	• Lifeline for Moms Perinatal Mental Health Toolkit. University of Massachusetts Medical School. https://repository.escholarship.umassmed.edu/handle/20.500.14038/44263
	Severity of depressive symptoms	• Mild: 10-14 • Moderate: 15-19 • Severe: ≥20		
	Screening instrument used	• PHQ-9 • EPDS		
	PHQ-9 Option Over the past 2 weeks, how often have you been bothered by any of the following problems? PHQ-1: Little interest or pleasure in doing things? PHQ-2: Feeling down, depressed or hopeless? PHQ-3: Trouble falling or staying asleep, or sleeping too much? PHQ-4: Feeling tired or having little energy? PHQ-5: Poor appetite or overeating? PHQ-6: Feeling bad about yourself - or that you are a failure or have let yourself or your family down? PHQ-7: Trouble concentrating on things, such as reading the newspaper or watching television? PHQ-8: Moving or speaking so slowly that other people could have noticed? Or the opposite— being so fidgety or restless that you have been moving around a lot more than usual PHQ-9: Thoughts that you would be better off dead, or of hurting yourself?	• Not at all • Several days • More than half the days • Nearly every day	Self-report	• Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001 Sep;16(9):606-13. doi: 10.1046/j.1525-1497.2001.016009606.x.

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
	EPDS Option EPDS-1: I have been able to laugh and see the funny side of things. EPDS-2: I have looked forward with enjoyment to things. EPDS-3: I have blamed myself unnecessarily when things when wrong. EPDS-4: I have been anxious or worried for no good reason. EPDS-5: I have felt scared or panicky for no good reason. EPDS-6: Things have been getting on top of me. EPDS-7: I have been so unhappy that I have had difficulty sleeping. EPDS-8: I have felt sad or miserable. EPDS-9: I have been so unhappy that I have been crying. EPDS-10: The thought of harming myself has occurred to me.	Response options vary by question (see "mapping/source" for details). Example: • As much as I always could • Not quite so much now • Definitely not so much now • Not at all	Self-report	• Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987 Jun;150:782-6. doi: 10.1192/bjp.150.6.782. PMID: 3651732.
Alcohol, tobacco, and substance use	TAPS-1: In the PAST 12 MONTHS, how often have you used any tobacco product (for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco)? TAPS-2: In the PAST 12 MONTHS, how often have you had (4 for women, or 5 for men) or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. TAPS-3: In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA? TAPS-4: In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? Prescription medications that may be used this way include Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone) Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin) Medications for ADHD (for example, Adderall or Ritalin)	• Daily or Almost Daily • Weekly • Monthly • Less than Monthly • Never	Self-report	• TAPS Tool. National Institute on Drug Abuse (NIDA). • NIDA Quick Screen V1.0. • National Institute on Alcohol Abuse and Alcoholism (NIAAA) Single Alcohol Screening Question.

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Substance / drug use	In your lifetime, which of the following substances have you ever used? Select all that apply.	• Cannabis • Cocaine • Prescription stimulants • Methamphetamine • Inhalants • Sedatives or sleeping pills • Hallucinogens • Street opioids • Prescription opioids • Other (specify)	Self-report	• NIDA Quick Screen V1.0.
	[If participant responds yes to any substance, ask]: In the PAST 3 MONTHS, how often have you used the substances you mentioned?	• Daily or Almost Daily • Weekly • Monthly • Once or Twice • Never		
Intimate partner violence	HARK-1: Within the last year, have you been humiliated or emotionally abused in other ways by your partner or ex-partner?	Yes / No	Self-report	• Sohal H, Eldridge S, Feder G. The sensitivity and specificity of four questions (HARK) to identify intimate partner violence: a diagnostic accuracy study in general practice. BMC Fam Pract. 2007 Aug 29;8:49. doi: 10.1186/1471-2296-8-49. PMID: 17727730; PMCID: PMC2034562.
	HARK-2: Within the last year, have you been afraid of your partner or ex-partner?	Yes / No		
	HARK-3: Within the last year, have you been raped or forced to have any kind of sexual activity by your partner or ex-partner?	Yes / No		
	HARK-4: Within the last year have you been kicked, hit, slapped, or otherwise physically hurt by your partner or ex-partner?	Yes / No		
Human milk / breastfeeding initiation and duration	Did you ever breastfeed or pump breast milk to feed your new baby, even for a short period of time?	Yes / No	Self-report	• PRAMS: https://www.cdc.gov/prams/about/index.html
	Are you currently breastfeeding or feeding pumped milk to your new baby?	Yes / No		
	How many weeks or months did you breastfeed or feed pumped milk to your baby?	• Less than 1 week • Number of weeks • Number of months		
Health insurance coverage and coverage changes	What kind of health insurance do you have now?	• Private health insurance (paid for by me, someone else, or through a job) • Medicaid (Site Medicaid name) • Site-specific option (Other government plan or program such	Self-report, EHR	• PRAMS: https://www.cdc.gov/prams/about/index.html

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
	During your most recent pregnancy, what kind of health insurance did you have? During the month before you got pregnant, what kind of health insurance did you have?	as SCHIP/CHIP) • Site-specific option (Other government plan or program not listed above such as MCH program, indigent program or family planning program) • Site-specific option (TRICARE or other military health care) • Site-specific option (IHS or tribal) • Other health insurance (please tell us) • I don't have any health insurance.		
Access to maternity care	County classification	• Maternity care desert • Low access to maternity care • Moderate access to maternity care • Full access to maternity care	March of Dimes database	• March of Dimes
Financial strain / material hardship	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? Select all that apply.	• Childcare • Clothing • Food • Housing • Internet/broadband • Phone • Transportation • Utilities • Medicine or any health care • Other	Self-report	• Proposed Use of Common Data Elements (CDEs) for NIH-Funded Clinical Research and Trials (NOT-OD-24-063) • PRAPARE Screening Tool
Food security	Hunger Vital Sign-1: Within the past 12 months, (I/we) worried whether (my/our) food would run out before (I/we) got money to buy more. Hunger Vital Sign-2: Within the past 12 months, the food (I/we) bought just didn't last, and (I/we) didn't have the money to get more.	• Often true • Sometimes true • Never true	Self-report	• The Hunger Vital Sign: https://childrenshealthwatch.org/public-policy/hunger-vital-sign/
Transportation insecurity	In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?	• Yes, it has kept me from medical appointments. • Yes, it has kept me from non-medical meetings, appointments, work or from getting things that I need. • No.	Self-report	• ACH Health-Related Social Needs • PRAPARE Screening Tool

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Life experiences	In your day-to-day life how often have any of the following things happened to you? EDS-1: You are treated with less courtesy or respect than other people. EDS-2: You receive poorer service than other people at restaurants or stores. EDS-3: People act as if they think you are not smart. EDS-4: People act as if they are afraid of you. EDS-5: You are threatened or harassed.	• Almost everyday • At least once a week • A few times a month • A few times a year • Less than once a year • Never	Self-report	• Williams DR et al. Everyday Discrimination Scale (Short Version). https://scholar.harvard.edu/davidrwilliams/node/32777 • Sternthal M, Slopen N, Williams DR. "Racial Disparities in Health: How Much Does Stress Really Matter?" Du Bois Review, 2011; 8(1): 95-113
	[If answer "A few times a year" or more frequently to at least one question:] What do you think is the main reason for these experiences? Select all that apply.	• Your Ancestry or National Origins • Your Sex • Your Race • Your Age • Your Religion • Your Height • Your Weight • Some other Aspect of Your Physical Appearance • Your Education or Income Level • Optional categories: A physical disability, a substance use disorder, your shade of skin color (NSAL), your tribe (SASH), • Other (specify)		
Current age	What is your age?	Number of years	Self-report, EHR	• ScHARE. • PhenX Toolkit. Current Age. https://www.phenxtoolkit.org/protocols/view/10102
Race and ethnicity	What is your race and/or ethnicity? Select all that apply.	• American Indian or Alaska Native • Asian • Black or African American • Hispanic or Latino • Middle Eastern or North African • Native Hawaiian or Pacific Islander • White	Self-report	• OMB Statistical Policy Directive No. 15: https://www.federalregister.gov/d/2024-06469/p-196

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Sex	What is your sex?	• Female • Male • Prefer not to answer	Self-report	• The White House, Executive Order 14168
Disability status	DIS-1: Are you deaf, or do you have serious difficulty hearing?	Yes / No	Self-report	• U.S. Department of Health and Human Services. https://www.cdc.gov/ncbddd/disabilityandhealth/datasets.html
	DIS-2: Are you blind, or do you have serious difficulty seeing, even when wearing glasses?	Yes / No		
	DIS-3: Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (5 years or older)	Yes / No		
	DIS-4: Do you have serious difficulty walking or climbing stairs? (5 years old or older)	Yes / No		
	DIS-5: Do you have difficulty dressing or bathing? (5 years old or older)	Yes / No		
	DIS-6: Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (15 years or older)	Yes / No		
Educational attainment	What is the highest grade or level of school you have completed or the highest degree you have received?	• Never attended / kindergarten only • __ grade (enter number 1-11) • 12th grade, no diploma • High school graduate • GED or equivalent • Some college, no degree • Associate degree: occupational, technical, or vocational program • Associate degree: academic program • Bachelor's degree (example: BA, AB, BS, BBA) • Master's degree (example: MA, MS, MEng, MEd, MBA) • Professional school degree (example: MD, DDS, DVM, JD)	Self-report, Vital records	• PhenX Toolkit. Educational Attainment - Individual. https://www.phenxtoolkit.org/protocols/view/11002 • U.S. Standard Certificate of Live Birth.

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
		• Doctoral degree (example: PhD, EdD)		
Partnership / marital status	What is your current marital status?	• Married • Divorced • Widowed • Separated • Never married • Living with partner • Prefer not to answer	Self-report	• All of Us Research Hub. https://www.researchallofus.org/data-tools/survey-explorer/social-determinants-survey/ • ScHARE.
Primary language	Do you speak a language other than English at home?	Yes / No / Prefer not to answer	Self-report	• U.S. Department of Health and Human Services. https://www.cdc.gov/ncbddd/disabilityandhealth/datasets.html
	[If yes:] What is this language?	Free text		
	Since you speak a language other than English at home, we are interested in your own opinion of how well you speak English. How well would you say you speak English?	• Very well • Well • Not well • Not at all		
Family income	How many family members, including yourself, do you currently live with?	Numeric	Self-report	• PRAPARE Screening Tool • PhenX Toolkit. Annual Family Income. https://www.phenxtoolkit.org/protocols/view/11102 • OMB in Statistical Policy Directive 14. https://www.census.gov/topics/income-poverty/poverty/about/history-of-the-poverty-measure/omb-stat-policy-14.html
	What is your best estimate of the total income of all family members from all sources, before taxes, in the last calendar year? [Consider your income and the income of all related family members who you currently live with; do not include income from roommates].	Numeric (dollars)		

Data Element	Question Text	Response Options	Data Sources	Mapping / Source
Current place of residence	Zip code	Numeric	Self-report	• PhenX Toolkit. Current Address. https://www.phenxtoolkit.org/protocols/view/10802 • Project 5 (COVID): https://cde.nlm.nih.gov/deView?tinyId=njQIyXM_By
	County	Free text		
Birthplace	Where were you born?	• United States (specify state) • Outside of US (specify name of foreign country or US territory • Prefer not to answer	Self-report	• PhenX Toolkit. Birthplace. https://www.phenxtoolkit.org/protocols/view/10201

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Annex 1: Detailed Biomedical Recommendations

Pregnancy / postpartum status

Minimum Data Elements
Researchers should collect the following minimum response options:

- Currently pregnant
- Pregnant in the past 12 months
- Neither

Notes: In addition to recording whether a participant is currently pregnant or was pregnant in the past 12 months, researchers should also record the gestational age and estimated due date (for those currently pregnant) and number of days postpartum (for those pregnant in the past 12 months). These are separate data elements described in detail elsewhere in this document.

Data Sources and Measurement Guidance
In clinical settings, the Alliance for Innovation on Maternal Health recommends verbal screening of patients for current or recent pregnancy within 12 months.[24] In research settings, the PhenX Pregnancy Working Group recommends using self-report in settings in which knowledge of pregnancy status is not critical to the study itself.[3] However, a pregnancy test is recommended if pregnancy status is vital to the study or if there is any potential risk to the participant or fetus if the participant is pregnant. Either of the following measurement protocols are recommended, depending on context and feasibility.

Recommended:

- Self-report: Ask *"Are you pregnant now?" and "Have you been pregnant in the past 12 months?"* Response options: Yes, No, Don't know. Questions are adapted from the PhenX Toolkit: https://www.phenxtoolkit.org/protocols/view/240602 and Alliance for Innovation on Maternal Health's Pregnancy Screening Statement: https://saferbirth.org/aim-pregnancy-screening-statement

- Bioassay: A pregnancy test should be conducted if it is necessary to know whether the subject is pregnant for research or clinical purposes. In these cases, the PhenX bioassay protocol is recommended: https://www.phenxtoolkit.org/protocols/view/240601

Gestational age and estimated due date

Minimum Data Elements
Estimated due date: year, month, and day
Gestational age: number of completed weeks

Data Sources and Measurement Guidance
Gestational age and estimated due date (EDD) should be recorded at the time a significant event occurs, such as diagnosis, hospital admission, or death. Measurement should adhere to American College of Obstetricians and Gynecologists (ACOG), the American Institute of Ultrasound in Medicine (AIUM), and the Society for Maternal–Fetal Medicine (SMFM) guidance, as described in their 2017 Committee Opinion[32]:

- "Ultrasound measurement of the embryo or fetus in the first trimester (up to and including 13 6/7 weeks of gestation) is the most accurate method to establish or confirm gestational age.
- If pregnancy resulted from assisted reproductive technology (ART), the ART-derived gestational age should be used to assign the EDD. For instance, the EDD for a pregnancy that resulted from in vitro fertilization should be assigned using the age of the embryo and the date of transfer.
- As soon as data from the last menstrual period (LMP), the first accurate ultrasound examination, or both are obtained, the gestational age and the EDD should be determined, discussed with the patient, and documented clearly in the medical record. Subsequent changes to the EDD should be reserved for rare circumstances, discussed with the patient, and documented clearly in the medical record.
- When determined from the methods outlined in this document for estimating the due date, gestational age at delivery represents the best obstetric estimate for the purpose of clinical care and should be recorded on the birth certificate. For the purposes of research and surveillance, the best obstetric estimate, rather than estimates based on the LMP alone, should be used as the measure for gestational age.
- A pregnancy without an ultrasound examination that confirms or revises the EDD before 22 0/7 weeks of gestational age should be considered suboptimally dated."

Recommended data sources are electronic health records or vital records. Self-reported data can be used as an alternative if these data sources are not available.

Recommended:

- EHR abstraction: The PhenX Pregnancy Work Group[3] endorsed a protocol for abstracting gestational age from medical records: https://www.phenxtoolkit.org/protocols/view/240902
- Vital records: Birth certificates include a field to report the gestational age of the infant at the time of birth.[33]

Alternative:

- Self-report: Should it not be feasible to determine gestational age via maternal chart review or vital records, the PhenX Pregnancy Work Group protocol for maternal interview can be used[3]; however, this is not preferred given the risk of recall bias: https://www.phenxtoolkit.org/protocols/view/240901

Date of delivery / end of pregnancy

Minimum Data Elements
Date of delivery / end of pregnancy: year, month, and day

Data Sources and Measurement Guidance
Researchers should capture the known or estimated year, month, and day the pregnancy ended. In the case of a live birth, this data element is the same as the date of the birth. Data may be obtained from EHR, discharge or claims data, vital records, or self-report.

Recommended:

- EHR abstraction/extraction: Researchers may abstract this information from medical records, or these elements may be extracted using natural language processing and other machine learning techniques. For example, "Method to Acquire Delivery Date Information from Electronic Health Records" or MADDIE is an algorithm for extracting patient delivery date from EHR.[34]
- Vital records: Birth certificates include a field to report the date of delivery of the infant; fetal death certificates include a field to report the date of delivery of the fetus.[33]
- Discharge / claims data: Codes in hospital discharge data or claims data can be used to identify the date of delivery or end of the pregnancy.
- Self-report: Ask *"On what date did you deliver?"* or *"On what date did your pregnancy end?"*

Days postpartum at time of event

Minimum Data Elements
Number of days since birth (or since pregnancy ended)

Data Sources and Measurement Guidance
Number of days postpartum should be recorded at the time a significant event occurs, such as diagnosis, hospital admission, or death. Ideally, timing should be captured as the number of days postpartum. If this is not feasible, researchers may record the number of weeks or months postpartum to provide a general sense of timing.

Number of days postpartum can be calculated from the delivery date (or the date the pregnancy ended) as recorded in medical records, discharge or claims data, vital records (e.g., birth certificate), or it can be captured by self-report. See data sources and measurement guidance for “Date of delivery / end of pregnancy.”

Plurality

Minimum Data Elements
Number of fetuses delivered live or dead at any time in the pregnancy

Data Sources and Measurement Guidance
Researchers should measure plurality in alignment with the definition from the National Center for Health Statistics[35]: "The number of fetuses delivered live or dead at any time in the pregnancy regardless of gestational age, or if the fetuses were delivered at different dates in the pregnancy."

Pregnancy outcome

Minimum Data Elements
Researchers should capture the following minimum response options:

- Live birth
- Stillbirth (>=20 weeks)
- Miscarriage / spontaneous abortion (<20 weeks)
- Abortion (induced)
- Ectopic pregnancy
- Prefer not to answer

Data Sources and Measurement Guidance
Researchers may obtain this data from EHR or self-report. Researchers should consider ethical, legal, and practical implications of collecting data on pregnancy outcome and identify any potential risks posed to study participants. These issues should be considered in procedures for obtaining informed consent and ensuring confidentiality (e.g., obtaining a Certificate of Confidentiality). For self-reported data, the PhenX protocol for maternal interview is recommended: https://www.phenxtoolkit.org/protocols/view/101301

Mode of delivery

Minimum Data Elements
Minimum response options:
- Spontaneous vaginal
- Forceps vaginal
- Vacuum vaginal
- Cesarean delivery
- Other (specify, e.g., breech extraction)

Data Sources and Measurement Guidance
Researchers may choose to collect more detailed information beyond the minimum categories. For example, cesarean deliveries may be further categorized as elective vs. emergency. Additionally, researchers may also collect information on attempted methods (e.g., vacuum extraction attempted, vaginal forceps attempted) before successful delivery mode. Researchers should prioritize data from EHR and vital records, with self-report as an alternative if these records are not available.

Recommended:
- EHR abstraction: Mode of delivery can be abstracted from medical records following the PhenX protocol.[3] See question 9: https://www.phenxtoolkit.org/protocols/view/241302
- Administrative data: Information about delivery mode may be available from ICD-10 codes: https://icd.who.int/browse10/2016/en#/O80-O84 and Current Procedural Terminology (CPT) codes: https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2022-chapter-7.pdf
- Vital records: Birth certificates include a field about the final route and method of delivery.[33] Fetal death certificates include a similar field.

Alternative:
- Self-report: The PhenX protocol for maternal interview may be used if medical records are not available.[3] In these cases, response options are vaginal or cesarean delivery, without additional specification on type of vaginal or cesarean delivery: https://www.phenxtoolkit.org/protocols/view/241301

Cardiovascular conditions

The Alliance for Innovation in Maternal Health (AIM) uses the term “cardiac conditions in obstetrical care” to refer to “disorders of the cardiovascular system which may impact maternal health.”[66]

Minimum Data Elements

Researchers should collect the following minimum data elements, aligned with AIM’s cardiac conditions in obstetrical care:

- Congenital Heart Disease (Y/N)
- Cardiac Valve Disorders (Y/N)
- Cardiomyopathies (Y/N)
- Arrhythmias (Y/N)
- Coronary Artery Disease (Y/N)
- Pulmonary Hypertension (Y/N)
- Other/Not Specified (Y/N)

Data Sources and Measurement Guidance

ICD-10 codes are recommended to identify patients with the above conditions or diagnoses. These codes[66] can usually be found in EHR and other administrative data sources, such as hospital discharge data (page 9): https://saferbirth.org/wp-content/uploads/Cardiac-Conditions-in-Obstetrical-Care-Patient-Safety-Bundle-2.pdf

Gestational diabetes
The American College of Obstetricians and Gynecologists (ACOG) defines gestational diabetes as “diabetes that starts during pregnancy.”[71]

Minimum Data Elements
- Gestational diabetes (Y/N)

Data Sources and Measurement Guidance
Recommended methods for capturing gestational diabetes include use of laboratory criteria, ICD codes, or EHR abstraction/extraction. Self-report can be used if these sources are not available. The following measurement protocols, specific to each data source, are recommended:
- Laboratory criteria: Labs tests may be administered as part of the study in adherence with current practices guidelines, or laboratory test data may be abstracted from medical records following the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/241001
- ICD-10 codes: ICD-10 codes can usually be found in EHR and other administrative data sources. The ICD code O24.4 may be used to identify cases of gestational diabetes: https://icd.who.int/browse10/2019/en#/O24
- Triangulation across EHR data elements: Researchers can review and triangulate across a combination of data elements found in EHR, such as past medical history, problem list, visit diagnosis, or provider notes. These elements may be extracted using natural language processing and other machine learning techniques or abstracted and reviewed by a trained reviewer. Abstractors should not include any diabetic conditions that were diagnosed prior to the current pregnancy or from a previous pregnancy.

Alternative:
- Self-report: Researchers can use the Pregnancy Risk Assessment Monitoring System (PRAMS) to collect self-reported data[20]: *"During your most recent pregnancy, did a healthcare provider tell you that you had gestational diabetes (diabetes that started during this pregnancy)"* Response options: Yes, No, Don’t know.

Hypertensive disorders of pregnancy
The American College of Obstetricians and Gynecologists (ACOG) defines chronic hypertension as "blood pressure that is higher than normal for a person's age, sex, and physical condition" and gestational hypertension as "high blood pressure that is diagnosed after 20 weeks of pregnancy."[69] Preeclampsia, eclampsia, and HELLP syndrome are disorders in pregnancy or after pregnancy that are linked to high blood pressure.

Minimum Data Elements
- Chronic hypertension (Y/N)
- Gestational hypertension (Y/N)
- Preeclampsia (Y/N)
- Eclampsia (Y/N)
- HELLP Syndrome (Y/N)

Data Sources and Measurement Guidance
Use of multiple data elements to identify hypertensive disorders of pregnancy is recommended as the most valid measurement approach. If the use of multiple data elements is not feasible, researchers may use ICD codes to identify patients with the above conditions or diagnoses. Alternatively, the self-report question in CDC's PRAMS may be used if neither of the above data sources are available or feasible.
- Triangulation across EHR data elements: Researchers should review and triangulate across a combination of data elements found in EHR, such as past medical history, problem list, visit diagnosis, or provider notes. These elements may be extracted using natural language processing and other machine learning techniques or abstracted and reviewed by a trained reviewer.
- ICD-10 codes: ICD-10 codes can usually be found in EHR and other administrative data sources, such as hospital discharge data[67] (page 10): https://saferbirth.org/wp-content/uploads/Severe-Hypertension-in-Pregnancy-Patient-Safety-Bundle.pdf
    - Hypertension (chronic / pre-gestational): I10-I15, O10.0
    - Gestational hypertension: O13.X
    - Preeclampsia: O14.0, O14.1, O14.9; O11.X
    - Eclampsia: O15.X
    - HELLP syndrome: O14.2X

Alternative:
- Self-report: If neither of the above approaches are feasible, researchers may collect self-report data using the following questions from the Pregnancy Risk Assessment Monitoring System (PRAMS)[20]:
    - *"During the 3 months before you got pregnant with your new baby, did you have high blood pressure or hypertension?"* Response options: Yes, No, Don't know
    - *"During your most recent pregnancy, did a healthcare provider tell you that you had any of the following health conditions: High blood pressure that started during pregnancy? Preeclampsia? Eclampsia?* Response options: Yes, No, Don't know

Obstetric hemorrhage
Obstetric hemorrhage refers to excessive bleeding during pregnancy, childbirth, or in the postpartum period; this broader definition encompasses specific conditions of antepartum and postpartum hemorrhage.

Minimum Data Elements
- Antepartum hemorrhage (Y/N)
- Postpartum hemorrhage (Y/N)

Antepartum Hemorrhage Data Sources and Measurement Guidance
For the purposes of CDE measurement, antepartum hemorrhage is defined as bleeding during pregnancy that occurs after the 20th week of gestation. Thus, researchers should apply a gestational age cut-off of 20 or more weeks to improve specificity in distinguishing cases of antepartum hemorrhage. Recommended data sources are ICD-10 diagnosis codes. The use of blood transfusion as a proxy indicator is also acceptable in contexts where the reason for transfusion can be determined. The following measurement protocols, specific to each data source, are recommended:
- ICD-10 diagnosis codes: ICD-10 codes are usually available in EHR and other administrative data sources, such as hospital discharge data: https://saferbirth.org/wp-content/uploads/Obstetric-Hemorrhage-Patient-Safety-Bundle-2.pdf.[64] Relevant ICD-10 codes include:
    - Antepartum hemorrhage: O46x
    - Placenta previa with hemorrhage: O41.1x, O44.3x, O44.5x
    - Placental abruption: O45.x
- Blood transfusion: Blood transfusion of at least 1 unit during pregnancy (20+ weeks) can be used as a proxy for antepartum hemorrhage in contexts where the reason for transfusion can be determined. Only transfusions to manage bleeding should be included; transfusions to treat anemia should be excluded. CMQCC[65] provides an example of ICD-10-PCS codes for use in coding transfusions in maternity patients (p. 182): https://www.cmqcc.org/resource/improving-health-care-response-obstetric-hemorrhage-toolkit-version-30-errata-72022

Postpartum Hemorrhage Data Sources and Measurement Guidance
ACOG defines postpartum hemorrhage (PPH) as "cumulative blood loss of greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process."[74] Use of multiple data elements to identify PPH cases is recommended as the most valid measurement approach. The use of blood transfusion as a proxy indicator for PPH is acceptable. The following measurement protocols, specific to each data source, are recommended:
- Triangulation across EHR data elements: Researchers review and triangulate across a combination of elements from EHR to identify PPH cases. Cases may be identified using natural language processing and other machine learning techniques, or they may be abstracted and classified by a trained reviewer. For example, Clapp et al. 2021 describes multiple elements from EHR that could be used to identify PPH cases[39]:
    1. Transfusion of at least 1 unit of packed red blood cells
    2. Estimated blood loss (EBL) of 1,000 mL documented in the delivery records
    3. Documentation of PPH in the provider notes
    4. 10 percentage point change between the admission and any postpartum hematocrit
    5. ICD-10 diagnosis code for PPH (e.g., O72.0, O72.1, O72.2)
- Blood transfusion: In circumstances where researchers do not have access to detailed information in EHR, they may use transfusion of at least 1 unit of blood during or after delivery as a proxy for PPH. CMQCC[65] provides an example of ICD-10-PCS codes for use

in coding transfusions in maternity patients (p. 182): https://www.cmqcc.org/resource/improving-health-care-response-obstetric-hemorrhage-toolkit-version-30-errata-72022

Note: While ICD codes were considered acceptable for identifying cases of antepartum hemorrhage, the Delphi panel does not recommend use of ICD codes alone as a valid measurement approach for PPH.

Placental disorders and complications

Placental disorders and complications are frequent causes of maternal and fetal morbidity and mortality. The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) define placenta accreta spectrum as “the range of pathologic adherence of the placenta, including placenta increta, placenta percreta, and placenta accreta.”[68] ACOG defines placenta previa as “a condition that causes the placenta to cover the opening of the uterus” and placenta abruption as “a condition that causes the placenta to separate from the uterus before the fetus is born”.[69]

Minimum Data Elements

Researchers should collect the following minimum data elements:

- Placenta previa (Y/N)
- Placental abruption (Y/N)
- Placenta accreta spectrum (Y/N)

Data Sources and Measurement Guidance

Researchers should review and triangulate across a combination of data elements, such as ultrasound reports, provider notes, and diagnosis codes found in EHR, to determine whether a patient has any of the above placental disorders or complications. Cases may be identified using natural language processing and other machine learning techniques, or they may be abstracted and classified by a trained reviewer.

Sepsis
The American College of Obstetricians and Gynecologists (ACOG) defines sepsis as "a life-threatening condition caused by a buildup of infectious toxins (usually from bacteria) in the blood."[69]

Minimum Data Elements
- Sepsis (Y/N)

Data Sources and Measurement Guidance
It is recommended that researchers use ICD codes or information abstracted from medical records to identify sepsis cases.
- ICD-10 codes: ICD-10 codes can usually be found in EHR and other administrative data sources and may be used to identify sepsis cases (pages 8-9)[70]: https://saferbirth.org/wp-content/uploads/Sepsis-in-Obstetric-Care-Patient-Safety-Bundle.pdf
- Triangulation across EHR data elements: Researchers can review and triangulate data found in EHR, such as past medical history, problem list, visit diagnosis, or provider notes. These elements may be extracted using natural language processing and other machine learning techniques or abstracted and reviewed by a trained reviewer.

Severe maternal morbidity
The American College of Obstetricians and Gynecologists (ACOG) defines severe maternal morbidity (SMM) as the "unintended outcomes of the process of labor and delivery that result in significant short-term or long-term consequences to a woman's health."[37]

Minimum Data Elements
- SMM event occurred (Y/N)
- Criteria used to determine SMM event occurred (CDC or ACOG-SMFM)
- Relevant code (specify which CDC ICD-10 code or ACOG-SMFM indicator)

Data Sources and Measurement Guidance
There is no consensus on the conditions or circumstances that should count as SMM. However, there are currently two widely used approaches for identifying SMM. Either protocol is recommended to measure severe maternal morbidity.
- Severe Maternal Morbidity Indicators (CDC)[38]**:** To identify delivery hospitalizations with SMM, CDC uses administrative hospital discharge data and ICD codes. These 21 indicators and corresponding ICD codes can identify delivery hospitalizations with SMM using administrative data starting in October 2015. Both ICD-9 and ICD-10 can be used to track SMM: https://www.cdc.gov/maternal-infant-health/php/severe-maternal-morbidity/icd.html
- Facility-based Severe Maternal Morbidity (ACOG-SMFM)[37]: To facilitate identification and review of SMM cases at the facility level, ACOG and SMFM recommend using two criteria to screen for SMM: 1) transfusion of 4 or more units of blood and/or 2) admission of a pregnant or postpartum woman to an ICU: https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2016/09/severe-maternal-morbidity-screening-and-review

Recommended:
- EHR or hospital discharge data are the recommended data source for identifying SMM.

Death during pregnancy / postpartum

Minimum Data Elements
Death occurred (Y/N)

Notes: In addition to recording whether a death occurred, researchers should also record the date of death, whether pregnant or postpartum at time of death, number of days postpartum at time of event (if applicable), and cause of death. These are separate data elements described in detail in subsequent entries.

Data Sources and Measurement Guidance
Several terms exist to describe a death that occurs during pregnancy or the postpartum period. Researchers conducting primary data collection should record any death, irrespective of cause, that occurs during the study timeframe. However, for the purpose of their study, researchers may use one or more of the following definitions, which differ based on time and cause of death:

- Pregnancy-associated death: A death during or within 1 year of the end of pregnancy, regardless of the cause. This includes accidental or incidental deaths.
- Pregnancy-related death: A death during or within 1 year of the end of pregnancy from any cause related to or aggravated by the pregnancy.
- Maternal death: The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Recommended:

- Vital records are the recommended data source for confirming the occurrence of a death.

Alternative:

- EHR: If vital records are not available, researchers may obtain information from EHR. However, deaths are not always uniformly captured in EHR. For example, if a patient is transferred to another facility, a death that occurs at the receiving facility may not be captured in the originating hospitals' EHR.

Cause of death during pregnancy / postpartum

Minimum Data Elements
To facilitate interoperability of datasets, researchers should use standardized systems for coding

- Pregnancy Mortality Surveillance System (PMSS)-MM codes: https://www.cdc.gov/maternal-mortality/media/pdfs/2024/05/mmria-form-v24-fillable-508.pdf (see Appendix A)
- ICD-10 codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593

Data Sources and Measurement Guidance
After a death occurs, the certifying physician, coroner, or medical examiner records the immediate cause of death and antecedent conditions on the official death certificate. State and federal vital statistics programs process these certificates and use ICD-10 to classify and code underlying and, if applicable, multiple causes of death. State-based maternal mortality review committees also review pregnancy-related or pregnancy-associated deaths that occur during and within 1 year of pregnancy. These committees review all available records, including vital records, medical records, and autopsy reports, to determine whether a death was pregnancy-related, the cause of death, and factors contributing to the death to make recommendations to prevent future deaths from occurring.

Recommended:
- Triangulation across multiple data sources: such as vital records, EHR, and autopsy reports, by a trained reviewer or review committee is recommended when feasible.

Alternative:
- A single data source: If not feasible, researchers may use either vital records, EHR, or autopsy reports for determining cause of death.

Date of death during pregnancy / postpartum

Minimum Data Elements
Date of death: year, month, and day

Data Sources and Measurement Guidance
Researchers should capture the actual or presumed year, month, and day of death. Recommended data sources are death certificate (vital records).[36] If not available, information may be obtained from EHR, discharge or claims data, or proxy-report by a family member.

Date of birth [neonate]

Minimum Data Elements
Date of birth: year, month, and day

Data Sources and Measurement Guidance
Researchers should capture the known or estimated year, month, and day of the neonate's birth. The recommended data source is vital records (i.e., birth certificate).[33] If not available, information may be obtained from EHR, discharge or claims data, or proxy-report by parent or caregiver.

Neonatal birth weight

Minimum Data Elements
Number of grams

Data Sources and Measurement Guidance
Measurement of birth weight is recommended in grams. Researchers should use data obtained from medical records, vital records (i.e., birth certificate), or physical examination. Proxy-reported birth weight should only be used if recommended data sources are not available. The following measurement protocols, specific to each data source, are recommended:

- EHR abstraction: Birth weight can be abstracted from medical records using the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/20201
- Vital records: Birth certificates include a field to record the birth weight of the neonate[33]
- Physical examination: The PhenX protocol for physical examination provides guidance for measurement of weight at birth: https://www.phenxtoolkit.org/protocols/view/20202

Alternative:

- Proxy self-report: If recommended data sources are not available, the PhenX protocol for caregiver-reported birth weight can be used: https://www.phenxtoolkit.org/protocols/view/20203

Sex of neonate

Minimum Data Elements
Response options:
- Male
- Female
- Sex not yet determined

Data Sources and Measurement Guidance
Researchers should capture sex of the neonate as male, female, or sex not yet determined. This information may be obtained from vital records including birth certificates[33], EHR, discharge or claims data, or proxy-report by parent or caregiver.

Neonatal death

Minimum Data Elements
Neonatal death occurred (Y/N)

Notes: In addition to recording whether a death occurred, researchers should also record the date of death and cause of death. These are separate data elements described in detail in the subsequent entries.

Data Sources and Measurement Guidance
Researchers should capture any neonatal deaths that occur before the 28th day of life in their study population, regardless of cause. Neonatal deaths be captured in accordance with the National Center for Health Statistics (NCHS) definition: "Death of a live-born child before the 28th day of life".[40] The recommended data sources are vital records or vital records in combination with other data sources. If these sources are not available, researchers may obtain information from EHR.

Cause(s) of neonatal death

Minimum Data Elements
To facilitate interoperability of datasets, researchers should use standardized systems for coding and classifying cause(s) of death, irrespective of data source(s). Researchers may use either:

- Primary cause of death codes in FIMR: https://ncfrp.org/wp-content/uploads/DataDictionary_CRS_v6-0.pdf (G6; pages 61-62)
- ICD codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593

Data Sources and Measurement Guidance
After a neonatal death occurs, the certifying physician, coroner, or medical examiner records the immediate cause of death and antecedent conditions on the official death certificate. State and federal vital statistics programs process these certificates and use ICD-10 to classify and code underlying and, if applicable, multiple causes of death. Fetal and infant mortality review (FIMR) committees also review a subset of fetal and infant deaths. These committees review available records, including vital records, medical records, and autopsy reports, to determine the primary cause of death.

Recommended:

- Triangulation across multiple data sources, such as vital records, EHR, and autopsy reports, by a trained reviewer or review committee is recommended, when feasible.

Alternative:

- A single data source: If not feasible, researchers may use either vital records, EHR, or autopsy reports for determining cause of death.

Date of neonatal death

Minimum Data Elements
Date of death: year, month, and day

Data Sources
Researchers should capture the actual or presumed year, month, and day of death. The recommended data source is vital records (i.e., death certificate).[36] If not available, information may be obtained from EHR, discharge or claims data, or proxy-report by a family member.

Fetal death

Minimum Data Element
Fetal death occurred (Y/N)

Data Sources and Measurement Guidance
The Model State Vital Statistics Act and Regulations defines fetal death as a "*death prior to the complete expulsion or extraction from its mother of a production of human conception, irrespective of the duration of the pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heart beats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.*"[41]

Fetal death reporting requirements are mandated by the state. Some states require reporting any fetal death irrespective of gestation, other requirements are based on gestation (e.g., 20 weeks or more), and others based on both gestation and birth weight. Given the variability of state reporting requirements, national statistics report fetal deaths with a stated or presumed period of gestation of 20 weeks or more. Researchers should use the definition most appropriate to their setting (e.g., specific state(s) vs. national data) and clearly document the definition used for their study.

The recommended data source for fetal deaths is vital records.[71]

Cause(s) of fetal death

Minimum Data Elements
To facilitate interoperability of datasets, researchers should use standardized systems for coding and classifying cause(s) of death, irrespective of data source(s). Researchers may use:

- Initial Causes of Fetal Death system used by Stillbirth Collaborative Research Network (SCRN): https://links.lww.com/AOG/A186
- Primary cause of death codes in FIMR: https://ncfrp.org/wp-content/uploads/DataDictionary_CRS_v6-0.pdf (pages 61-62)
- ICD codes: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3593

Data Sources and Measurement Guidance
After a fetal death occurs, the certifying physician, coroner, or medical examiner records the immediate cause of death and antecedent conditions on the official fetal death report. State and federal vital statistics programs process these reports and use ICD-10 to classify and code underlying and, if applicable, multiple causes of death. Fetal and infant mortality review (FIMR) committees also review a subset of fetal and infant deaths. These committees review available records, including vital records, medical records, and autopsy reports, to determine the primary cause of death and factors contributing to the death to make recommendations to improve future outcomes.

The recommended measurement approach is triangulation across multiple data sources by a trained reviewer or review committee, when feasible.

Recommended:

- Triangulation across multiple data sources, such as vital records, EHR, and autopsy reports, by a trained reviewer or review committee is recommended, when feasible.

Alternative:

- Reviewed vital statistics data: If not feasible, use of vital statistics data published after review by state or federal statistics programs is recommended.

Note: Use of data from fetal death reports alone is NOT recommended due to concerns about their validity.

Timing of fetal death
This data element captures when the fetus died with respect to labor and assessment.

Minimum Data Elements
Timing should be captured using the following minimum response options, aligned with those used in the US Standard Report of Fetal Death[73]:

- Dead at time of first assessment, no labor ongoing;
- Dead at time of first assessment, labor ongoing;
- Died during labor, after first assessment; and
- Unknown time of fetal death.

Data Sources and Measurement Guidance
The recommended data source is the fetal death report (i.e., vital statistics). If not available, information may be obtained from medical records or proxy-report by a family member.

Height [maternal]
Minimum Data Elements
Number of centimeters

Data Sources and Measurement Guidance
Researchers should measure height in centimeters. If data are originally recorded in inches, it may be converted into centimeters for the purpose of data standardization.

Recommended:

- Physical examination: Standing height is measured from the top of the participant's head to his or her heels, as described in the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/20706
- EHR abstraction: This information may be available in the past medical history, problem list, visit diagnosis, or provider notes.

Alternative:

- Vital records: Birth certificates have a field that captures the mother's height in feet/inches.[33]
- Self-report: Self-reported height can be recorded using the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/20707. Ask: *"How tall {are you/is [participant]} without shoes?"* However, self-reported height values are considered less accurate.

Pre-pregnancy weight

Minimum Data Elements
Number of kilograms

Data Sources and Measurement Guidance
Measurement of pre-pregnancy weight is recommended in kilograms. If data are originally recorded in pounds, it may be converted into kilograms for the purpose of data standardization.

Recommended:

- EHR abstraction: This information may be available in the past medical history, problem list, visit diagnosis, or provider notes.

Alternative:

- Self-report: Self-reported weight values are considered less accurate. However, if the above sources are not available, researchers may record self-reported pre-pregnancy weight, following the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/21301. Ask *"Just before you got pregnant with your current pregnancy, how much did you weigh?"*

Weight (current)

Minimum Data Elements
Number of kilograms

Data Sources and Measurement Guidance
Measurement of current weight is recommended in kilograms. If data are originally recorded in pounds, it may be converted into kilograms for the purpose of data standardization.

Recommended:

- Physical examination: Weight is measured using a digital floor scale. The instrument should be calibrated daily using standardized weights, and a log of calibration results should be maintained. For example, following this PhenX protocol: https://www.phenxtoolkit.org/protocols/view/21503
- EHR abstraction: Information on current weight may be recorded in the EHR.

Note: Self-reported weight values are considered less accurate, particularly during pregnancy when weight changes are common. We do not recommend researchers capture self-reported current weight.

Gestational weight gain

Minimum Data Elements
Number of kilograms

Data Sources and Measurement Guidance
Measurement of gestational weight gain is recommended in kilograms. If data are originally recorded in pounds, it may be converted into kilograms for the purpose of data standardization.

Recommended:

- Physical examination: Total weight gain can be calculated at the end of pregnancy using a self-reported pre-pregnancy weight and weight measured at the last prenatal or research visit before delivery, following this PhenX protocol: https://www.phenxtoolkit.org/protocols/view/21303
- EHR abstraction: Most obstetric practices and prenatal clinics use a standardized form to chart prenatal course. Total gestational weight gain is calculated by subtracting the pre-pregnancy weight from the weight at the final prenatal visit, usually within a week of delivery. Weight is occasionally measured at delivery and can be used for this calculation if membranes are still intact at the time of weighing. PhenX protocol: https://www.phenxtoolkit.org/protocols/view/21302

Alternative:

- Self-report: Self-reported weight values are considered less accurate. However, if the above sources are not available, researchers may use self-reported information following the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/21301. Ask: *"How much weight have you gained during this pregnancy?"*

Pregnancy history

Minimum Data Elements
Researchers should collect the following minimum elements about a patient's pregnancy history:

- Gravidity: number of pregnancies, current and past, regardless of pregnancy outcome
- Parity: number of pregnancies reaching ≥20 weeks gestation, regardless of number of fetuses or outcome (includes live births and stillbirths)
- Abortus: number of pregnancies that were lost for any reason before 20 weeks gestation, including induced abortions and miscarriages
- Term or duration of previous pregnancies: Preferably, this should be captured as # weeks gestation for all previous pregnancies. If data on # weeks not available / feasible to collect, gestational age categories (e.g., preterm or term) may be used.

Data Source and Measurement Guidance
It is recommended that researchers use EHR data to measure the above elements:

- EHR: Data may be obtained from diagnosis and procedure codes, demographics, and clinical notes. For example, Callahan et al. (2022) describes a common data model for identifying these attributes in EHR.[42]

Alternative:

- Self-report: If researchers are unable to access a patient's EHR, they may collect information via maternal interview. Researchers should use questions 1-4 of the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/101301

Prior cesarean delivery

Minimum Data Elements
Prior cesarean (Y/N)

Data Source and Measurement Guidance
Researchers should capture whether the patient had a cesarean delivery prior to the current pregnancy. Prior cesarean delivery can be ascertained using ICD codes, abstraction from medical records, or self-report.

Recommended:

- ICD codes: ICD codes may be used to identify cases using administrative data or EHR: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=0CD1BE9C-1351-452E-A904-50441CB98B16 and https://athena.ohdsi.org/search-terms/terms?query=repeat+cesarean
- EHR abstraction: This information may be available in the past medical history, problem list, visit diagnosis, or provider notes.
- Self-report: The PhenX interview protocol may be used to record data on prior cesarean delivery: https://www.phenxtoolkit.org/protocols/view/241301 . Ask: "*Before you had your new baby, did you ever have a baby by cesarean delivery or c-section (when a doctor cuts through the mother's belly to bring out the baby)*?" Response options: Yes, No, Don't know.

Chronic (pregestational) diabetes
The American College of Obstetricians and Gynecologists (ACOG) defines diabetes as a "condition that causes high levels of sugar in the blood." Pregestational diabetes refers to "diabetes that existed before pregnancy and may be diagnosed early in pregnancy".[71]

Minimum Data Elements
- Chronic (pregestational) diabetes (Y/N)

Data Sources and Measurement Guidance
Recommended:
- ICD-10 codes: ICD-10 codes can usually be found in EHR and other administrative data sources. ICD codes may be used to identify cases of diabetes mellitus disorder prior to the current pregnancy using administrative data or EHR. https://athena.ohdsi.org/search-terms/terms/201820 and https://athena.ohdsi.org/search-terms/terms?conceptClass=ICD10+code&page=1&pageSize=15&query=diabetes+mellitus&boosts
- Triangulation across EHR data elements: Researchers can review and triangulate across a combination of data elements found in EHR, such as past medical history, problem list, visit diagnosis, or provider notes. These elements may be extracted using natural language processing and other machine learning techniques or abstracted and reviewed by a trained reviewer.

Alternative:
- Self-report: If none of these sources are available, information may be obtained by self-report using the Pregnancy Risk Assessment Monitoring System (PRAMS)[20] question: *" During the 3 months before you got pregnant with your new baby, did you have any of the following health conditions?...Type 1 or Type 2 diabetes"*. Response Options: Yes, No.

Comorbidities
Researchers should use the expanded obstetric comorbidity scoring tool developed by Leonard et al. in 2020 which uses ICD-10-CM diagnosis and procedure codes to summarize and adjust for comorbidities and other risk factors in maternal health research. This index considers the following 27 patient-level risks factors for severe maternal morbidity.[43]

Minimum Data Elements
Obstetric comorbidity score (numeric score calculated using methods in Leonard et al. 2020)[43]
Yes/No for each of the 27 patient-level risk factors:

- Anemia, preexisting
- Asthma, acute or moderate/severe
- Bariatric surgery
- Bleeding disorder, preexisting
- Cardiac disease, preexisting
- Chronic hypertension
- Chronic renal disease
- Connective tissue or autoimmune disease
- Gastrointestinal disease
- Gestational diabetes mellitus
- HIV/AIDS
- Major mental health disorder
- Neuromuscular disease
- Placenta accreta spectrum
- Placenta previa, complete or partial
- Placental abruption
- Preeclampsia with severe features
- Preeclampsia without severe features or gestational hypertension
- Preexisting diabetes mellitus
- Preterm birth (<37 weeks)
- Previous cesarean birth
- Pulmonary hypertension
- Substance use disorder
- Thyrotoxicosis
- Twins/multiple pregnancy
- Maternal age ≥ 35 years
- BMI at delivery ≥ 40

Data Source and Measurement Guidance
Researchers should use ICD-10-CM diagnosis and procedures codes available in administrative records or EHR. For a list of relevant ICD-10 codes, researchers may consult the appendix of the referenced paper: https://cdn-links.lww.com/permalink/aog/b/aog_136_3_2020_07_02_leonard_20-592_sdc1.pdf

Maternal Intensive Care Unit (ICU) admission

Minimum Data Elements
Maternal ICU admission (Y/N)

Data Source and Measurement Guidance
Researchers should capture maternal admissions to the intensive care unit (ICU). This includes ICU admissions during delivery hospitalization, as well as ICU admissions that occur during pregnancy or the postpartum period. Admission to the ICU should be ascertained by medical record abstraction or using relevant codes in administrative data.

Recommended:

- Abstraction from EHR: ACOG and SMFM recommend facilities put in place procedures to identify and review cases when a patient is admitted to an ICU. Such information can be abstracted from medical records.[37]
- Claims Data: ICU admission can be identified using a combination of Revenue Center Codes or a derived ICU indicator code: https://resdac.org/cms-data/variables/intensive-care-unit-icu-indicator-code

Neonatal Intensive Care Unit (NICU) admission or step-up care

Minimum Data Elements
Researchers should capture the highest level of medical care provided to the infant using the following minimum categories:

- Well newborn nursery
- Special care nursery
- Admission to NICU
- Admission to regional NICU

Note: This data element measures the intensity of medical care provided to an infant and not the NICU facility certification level assigned by the state.

Data Sources and Measurement Guidance
Information on the highest level of medical care provided to the infant, including admission to special care nursery or NICU, may be documented in EHR or other administrative data sources, such as claims records. The recommended measurement approach is abstraction from medical records if feasible. If not, researchers may rely on revenue center codes in claims data.

Recommended:

- EHR abstraction: Abstraction guidance from the Joint Commission suggests reviewing nursing notes, discharge summaries, physician progress notes, and other supporting documentation (NICU admission assessment, NICU flow sheet) for documentation that the newborn was admitted to special care nursery or NICU: https://manual.jointcommission.org/releases/TJC2018A/DataElem0275.html

Alternative:

- Claims Data: The highest level of care provided to the infant can be identified using revenue center codes on any of the claim records included in the stay. Relevant revenue codes for newborn care include 0171 (Newborn Level I, Well newborn nursery), 0172 (Newborn Level II, Special care nursery), 0173 (Newborn Level III, NICU), 0174 (Newborn Level IV, Regional NICU): https://www.aha.org/system/files/media/file/2020/01/RC%2017x.pdf

Annex 2: Detailed Psychosocial Recommendations

Depressive disorders
Researchers should use either the Patient Health Questionnaire (PHQ-9)[72] or Edinburgh Postnatal Depression Scale (EPDS)[73] to measure depressive symptoms in perinatal populations. To facilitate data interoperability (while allowing some flexibility in choice of instrument), scores can be categorized as positive or negative screens and, if positive, by severity of depressive symptoms. Researchers should use professional guidelines to categorize scores, such as those published in the ACOG Lifeline for Moms perinatal mental health toolkit.[45]

Minimum Data Elements
- Presence of depressive symptoms (yes ≥10 or no <10)
- Severity of depressive symptoms (mild: 10-14, moderate: 15-19, severe: ≥20)
- Screening instrument used (PHQ-9 or EPDS)
- Item-responses*

**Researchers may use either the PHQ-9 or EPDS to screen for the presence of depressive symptoms. Responses to each item should be recorded to facilitate comparisons across datasets.*

PHQ-9[74]: Over the past 2 weeks, how often have you been bothered by any of the following problems?
Response options: Not at all; Several days; More than half the days; Nearly every day
- Little interest or pleasure in doing things?
- Feeling down, depressed or hopeless?
- Trouble falling or staying asleep, or sleeping too much?
- Feeling tired or having little energy?
- Poor appetite or overeating?
- Feeling bad about yourself-
  or that you are a failure or have let yourself or your family down?
- Trouble concentrating on things, such as reading the newspaper or watching television?
- Moving or speaking so slowly that other people could have noticed? Or the opposite— being so fidgety or restless that you have been moving around a lot more than usual
- Thoughts that you would be better off dead, or of hurting yourself?

EPDS[75]: Select the answer that comes closest to how you have felt in the past 7 days, not just how you feel today.
- I have been able to laugh and see the funny side of things. *(Response options: As much as I always could; Not quite so much now; Definitely not so much now; Not at all)*
- I have looked forward with enjoyment to things. *(Response options: As much as I ever did; Rather less than I used to; Definitely less than I used to; Hardly at all)*
- I have blamed myself unnecessarily when things when wrong. *(Response options: Yes most of the time; Yes some of the time; Not very often; No never)*
- I have been anxious or worried for no good reason. *(Response options: No not at all; Hardly ever; Yes sometimes; Yes very often)*
- I have felt scared or panicky for no good reason. *(Response options: Yes quite a lot; Yes sometimes; No not much; No not at all)*
- Things have been getting on top of me. *(Response options: Yes most of the time I haven't been able to cope at all; Yes sometimes I haven't been coping as well as usual; No most of the time I have coped quite well; No I have been coping as well as ever)*

- I have been so unhappy that I have had difficulty sleeping. *(Response options: Yes most of the time; Yes sometimes; Not very often; No not at all)*
- I have felt sad or miserable. *(Response options: Yes most of the time; Yes quite often; Not very often; No not at all)*
- I have been so unhappy that I have been crying. *(Response options: Yes most of the time; Yes quite often; Only occasionally; No never)*
- The thought of harming myself has occurred to me. *(Response options: Yes quite often; Sometimes; Hardly ever; Never)*

Data Sources and Measurement Guidance
Data are collected by self-report.

Measurement Guidance – Safety and Ethical Considerations

Study participants who screen positive for depressive symptoms may require follow-up and referral. This is especially true for any participants who report self-harm or suicidal ideation. Safety and ethical issues should be considered in procedures for obtaining informed consent, safety monitoring, and response to safety risks.

Alcohol, tobacco, and substance use (combined measure)
Researchers should use the 4-item measure of tobacco use, alcohol use, prescription medication misuse, and illicit substance use in the past year. These 4-items align with the National Institute on Drug Abuse (NIDA) Quick Screen[46] and TAPS-1[47], and the alcohol item aligns with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Single Alcohol Screening Question.[48] The question is also used in the Accountable Health Communities Health-Related Social Needs Screening Tool.[49] The US Preventative Services Task Force recommends these for use in clinical care to screen patients for various substance use concerns[50], and the NIDA Clinical Trials Network recommends this as a CDE.[51]

Minimum Data Elements
Questions:
1. In the PAST 12 MONTHS, how often have you used any tobacco product (for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco)?
2. In the PAST 12 MONTHS, how often have you had (4 for women, or 5 for men) or more drinks containing alcohol in one day? *One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.*
3. In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?
4. In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? *Prescription medications that may be used this way include: Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone) Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin) Medications for ADHD (for example, Adderall or Ritalin)*

Response options:
- Daily or Almost Daily
- Weekly
- Monthly
- Less than Monthly
- Never

Data Sources and Measurement Guidance
Data are collected by self-report.

Substance / drug use
The first two questions of the NIDA-modified ASSIST (version 2.0)[46] are recommended to measure use of specific substances in the respondent's lifetime and the frequency of use in the past 3 months.

Minimum Data Elements
Question 1: In your lifetime, which of the following substances have you ever used?
- Cannabis (Y/N)
- Cocaine (Y/N)
- Prescription stimulants (Y/N)
- Methamphetamine (Y/N)
- Inhalants (Y/N)
- Sedatives or sleeping pills (Y/N)
- Hallucinogens (Y/N)
- Street opioids (Y/N)
- Prescription opioids (Y/N)
- Other (Y/N) (If yes, specify)

Question 2 (if participant responds yes to any of the drugs in the previous question, ask): In the past three months, how often have you used the substances you mentioned?
- Daily or Almost Daily
- Weekly
- Monthly
- Once or Twice
- Never

Data Sources and Measurement Guidance
Data are collected by self-report.

Intimate partner violence
The 4-item Humiliation, Afraid, Rape, and Kick (HARK)questionnaire is recommended for measurement of intimate partner violence.[52]

Minimum Data Elements
Question 1: Within the last year, have you been humiliated or emotionally abused in other ways by your partner or ex-partner?
Question 2: Within the last year, have you been afraid of your partner or ex-partner?
Question 3: Within the last year, have you been raped or forced to have any kind of sexual activity by your partner or ex-partner?
Question 4: Within the last year have you been kicked, hit, slapped, or otherwise physically hurt by your partner or ex-partner?
Response options: Yes, No

Data Sources and Measurement Guidance
Data are collected by self-report.

Measurement Guidance – Safety and Ethical Considerations

Study participants who screen positive for intimate partner violence may require follow-up and referral. Safety and ethical issues will need to be considered in procedures for obtaining informed consent, safety monitoring, and response to safety risks.

Human milk / breastfeeding initiation and duration
The set of 3 questions from the Centers for Disease Control Pregnancy Risk Assessment Monitoring System (PRAMS) are recommended to measure breastfeeding initiation and duration.[53]

Minimum Data Elements
Question: Did you ever breastfeed or pump breast milk to feed your new baby, even for a short period of time?
Response options: Yes or No

Question 2: Are you currently breastfeeding or feeding pumped milk to your new baby?
Response options: Yes or No

Question 3: How many weeks or months did you breastfeed or feed pumped milk to your baby?

Response options:
- Less than 1 week
- ____ Weeks
- ____ Months

Data Sources and Measurement Guidance
Data are collected by self-report.

Health insurance coverage and coverage changes
Recommended questions about health insurance coverage and changes in coverage are adapted from the Centers for Disease Control and Prevention Pregnancy Risk Assessment Monitoring System (PRAMS).[54]

Minimum Data Elements
Question 1: What kind of health insurance do you have now?
Question 2: During your most recent pregnancy, what kind of health insurance did you have?
Question 3: During the month before you got pregnant, what kind of health insurance did you have?

Response options:
- Private health insurance (paid for by me, someone else, or through a job)
- Medicaid (Site Medicaid name)
- Site-specific option (Other government plan or program such as SCHIP/CHIP)
- Site-specific option (Other government plan or program not listed above such as MCH program, indigent program or family planning program)
- Site-specific option (TRICARE or other military health care)
- Site-specific option (IHS or tribal)
- Other health insurance. Please tell us: _____
- I didn't have any health insurance during the month before I got pregnant. / I didn't have any health insurance during my pregnancy. / I don't have any health insurance now.

Data Sources and Measurement Guidance
As an alternative to the self-reported protocols above, the same information may be obtained from the patient's medical or administrative records. This information should be recorded using, at a minimum, the response options above and separately for each time period (before, during, and after pregnancy). Also, researchers should note that the phrasing above reflects how to ask questions retrospectively during the postpartum period; the phrasing can be adapted if enrolling study participants during pregnancy and collecting data longitudinally.

Access to maternity care
The March of Dimes' indicator for "Access to Maternity Care" is recommended to categorize geographic access to maternity care.[55]

Minimum Data Elements
County classification:

- Maternity care desert [county has no hospitals providing obstetric care, no birth centers, no obstetrician gynecologist (OB/GYN), and no certified nurse midwives].
- Low access to maternity care [county has one or less hospital offering obstetrics services and fewer than 60 obstetrics providers per 10,000 births, and the proportion of women without health insurance is 10 percent or greater].
- Moderate access to maternity care [county has one or less hospital offering obstetrics services and fewer than 60 obstetrics providers per 10,000 births, and the proportion of women without health insurance is less than 10 percent].
- Full access to maternity care [county has either two or more hospitals offering obstetrics services or 60 or more obstetrics providers per 10,000 births].

Data Sources and Measurement Guidance
This indicator uses area health resource files to classify counties into one of four categories based on criteria above. Researchers will need to capture data on county of residence for their study participants to determine their access level.

Financial strain / material hardship
Researchers are recommended to use this single question (https://cde.nlm.nih.gov/formView?tinyId=n46lJ2U90F) proposed by NIH as a high-level CDE for measuring social determinants of health in their Request for Information (NOT-OD-24-063) released in February 2024.[56] The NIH-funded ScHARe[57] and Multiple Chronic Diseases Disparities Research Consortium[22] uses this CDE, and the PRAPARE screening tool asks a similar question.[58]

Minimum Data Element
Question: 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? Select all that apply.
Response options (y/n):
- Childcare
- Clothing
- Food
- Housing
- Internet/broadband
- Phone
- Transportation
- Utilities
- Medicine or any health care
- Other

Data Sources and Measurement Guidance
Data are collected by self-report.

Food security
The 2-item Hunger Vital Sign Screening Tool is recommended to measure food security.[59] This 2-item screening tool is based off the USDA Household Food Security Survey and has been used in medical and community-based settings around the country to identify households at risk of food insecurity.

Minimum Data Element
Questions: Some people have made the following statements about their food situation. Please answer whether the statements were OFTEN, SOMETIMES, or NEVER true for you and your household in the last 12 months.

- Within the past 12 months, (I/we) worried whether (my/our) food would run out before (I/we) got money to buy more.
- Within the past 12 months, the food (I/we) bought just didn't last, and (I/we) didn't have the money to get more.

Response options:

- Often true
- Sometimes true
- Never true

Data Sources and Measurement Guidance
Data are collected by self-report. The 2-item Hunger Vital Sign Screening Tool is part of the longer 6-item and 18-item versions of the US Adult Food Security Survey Module[60]; researchers may use the longer versions if they wish, but at a minimum all researchers should collect this 2-item bundle.

Transportation insecurity
The question-and-responses used in the Accountable Health Community Health-Related Social Needs Screening Tool[49] and the PRAPARE screening tool are recommended for measurement of transportation insecurity[58]. The Multiple Chronic Diseases Disparities Research Consortium also recommends this CDE.[22]

Minimum Data Elements
Question: In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?
Response options:
- Yes, it has kept me from medical appointments.
- Yes, it has kept me from non-medical meetings, appointments, work or from getting things that I need.
- No.
- I chose not to answer this question.

Data Sources and Measurement Guidance
Data are collected by self-report.

Life experiences
The abbreviated, 5-question version of the Everyday Discrimination Scale is recommended for standardized measurement.[61]

Minimum Data Elements
Question: In your day-to-day life how often have any of the following things happened to you?
- You are treated with less courtesy or respect than other people.
- You receive poorer service than other people at restaurants or stores.
- People act as if they think you are not smart.
- People act as if they are afraid of you.
- You are threatened or harassed.

Response options:
- Almost everyday
- At least once a week
- A few times a month
- A few times a year
- Less than once a year
- Never

Follow-up Question (Asked only of those answering "A few times a year" or more frequently to at least one question): What do you think is the main reason for these experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

Response options:
- Your Ancestry or National Origins
- Your Sex
- Your Race
- Your Age
- Your Religion
- Your Height
- Your Weight
- Some other Aspect of Your Physical Appearance
- Your Education or Income Level

Optional additional response options:
- A physical disability
- A substance use disorder
- Your shade of skin color (NSAL)
- Your tribe (SASH)
- Other (SPECIFY) _____

Data Sources and Measurement Guidance
Data are collected by self-report.

Current age

Minimum Data Element
Age in years

Data Sources and Measurement Guidance
Researchers should capture the current age of an adult participant in years via self-report or by calculating their age using the participant's date of birth. Researchers should adhere to either of the following protocols:

- Current age (years): Researchers can ask the number of years or months that the person has been alive adapted from the ScHARe protocol.[57] Ask "*What is (your / the person's) age?"* https://cde.nlm.nih.gov/deView?tinyId=PDjBiGXjO
- Current age (date of birth): Current age can be calculated using the respondent's date of birth (MM/DD/YYYY) and the date of the interview. Ask "*What is your birthdate?"* If participant does not know, ask "*How old are you?"* Researchers may refer to this suggested protocol: https://www.phenxtoolkit.org/protocols/view/10102

Race and ethnicity
Researchers are recommended to collect data on race and ethnicity in accordance with the Office of Management and Budget's (OMB) *Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15)*, as most recently revised in March 2024.

Minimum Data Elements
Question: What is your race and/or ethnicity? Select all that apply.
Response options include 7 minimum categories:
- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Middle Eastern or North African
- Native Hawaiian or Pacific Islander
- White

Data Sources and Measurement Guidance
Data are collected by self-report. OMB provides examples of different formats for these minimum categories, as well as more detailed response options at: https://www.federalregister.gov/d/2024-06469/p-196

Sex

Minimum Data Elements
What is your sex?

Response options:
- Female
- Male
- Prefer not to answer

Data Sources and Measurement Guidance
Data are collected by self-report.

Disability status
The Health and Human Services (HHS) data standard for measuring disability status is recommended.[62]

Minimum Data Elements
Response options are Yes or No.
1. Are you deaf, or do you have serious difficulty hearing?
2. Are you blind, or do you have serious difficulty seeing, even when wearing glasses?
3. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (5 years or older)
4. Do you have serious difficulty walking or climbing stairs? (5 years old or older)
5. Do you have difficulty dressing or bathing? (5 years old or older)
6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (15 years or older)

Data Sources and Measurement Guidance
Data are collected by self-report. Researchers should use this six-item set of questions used on the American Community Survey and other major surveys. OMB has encouraged the use of these questions set by federal agencies due to the extensive testing and development of these measures, including the findings that alternative measures did not test as well. The six items represent a minimum standard and the questions and answer categories cannot be changed. Additional questions on disability may be added to any survey as long as the minimum standard is included.

Example of formats and recommendations are shown here:
https://cde.nlm.nih.gov/deView?tinyId=0md12WGtZXE

Educational attainment
Researchers should measure educational attainment based on the highest level of schooling completed.

Minimum Data Elements
Question: What is the highest grade or level of school you have completed or the highest degree you have received?

Response options:
- Never attended / kindergarten only
- __ grade (enter number 1-11)
- 12th grade, no diploma
- High school graduate
- GED or equivalent
- Some college, no degree
- Associate degree: occupational, technical, or vocational program
- Associate degree: academic program
- Bachelor's degree (example: BA, AB, BS, BBA)
- Master's degree (example: MA, MS, MEng, MEd, MBA)
- Professional school degree (example: MD, DDS, DVM, JD)
- Doctoral degree (example: PhD, EdD)
- Refused
- Don't know

Data Sources and Measurement Guidance
There are multiple ways to gather data on a participant's educational attainment, including by self-report or vital records. Either of these two protocols are recommended:
- Self-Report: This single question is used by the Census and National Health and Nutrition Education Survey (NHANES): https://www.phenxtoolkit.org/protocols/view/11002
    - *Question:* What is the highest grade or level of school you have completed or the highest degree you have received?
    - *Response Options:* 24 response options ranging from no formal schooling to academic doctorate degree.
- Vital records: Birth certificates[33] provide the highest level of schooling reached by a parent at the time of their child's birth, and death certificates provide the highest level of schooling reached by the individual at the time of their death: https://www.cdc.gov/nchs/data/dvs/birth11-03final-ACC.pdf

Partnership / marital status
Researchers should capture partnership / marital status using the standardized question-response options used by the Multiple Chronic Diseases Disparities Research Consortium[22], All of Us project[21], and ScHARe[57].

Minimum Data Elements
Question: What is your current marital status?
Response options:
- Married
- Divorced
- Widowed
- Separated
- Never married
- Living with partner
- Prefer not to answer

Data Sources and Measurement Guidance
Data are collected by self-report.

Primary language
Researchers should ask the 2-part question about languages spoken and English proficiency in accordance with the Department of Health and Human Services' standard for primary language: https://www.cdc.gov/ncbddd/disabilityandhealth/datasets.html.[62]

Minimum Data Elements
Question 1: Do you speak a language other than English at home?
Response options:
- Yes
- No
- Prefer not to answer

Question 2 [if yes:] What is this language?
Specify: _____

Question 3: Since you speak a language other than English at home, we are interested in your own opinion of how well you speak English. How well would you say you speak English?

Response options:
- Very well
- Well
- Not well
- Not at all

Data Sources and Measurement Guidance
Data are collected by self-report.

Family income
Researchers are recommended to use a set of two questions, adapted from the PhenX toolkit and the PRAPARE screening tool[58], to measure annual family income and calculate poverty level. Poverty levels are calculated by summing incomes of all related persons who live together, in accordance with the Office of Management and Budget's (OMB) Statistical Policy Directive 14.[63]

Minimum Data Elements
Question 1: How many family members, including yourself, do you currently live with?
Response: ____ [number]

Question 2: What is your best estimate of the total income of all family members from all sources, before taxes, in the last calendar year? [Consider your income and the income of all related family members who you currently live with; do not include income from roommates].
*Response: $*_____ [amount]

Data Sources and Measurement Guidance
Data are collected by self-report. If the respondent doesn't know their family's total income, the PhenX protocol (https://www.phenxtoolkit.org/protocols/view/11102) proceeds to ask several questions to determine whether the income level was less than established poverty thresholds. Of note, this question asks about the income of all related persons living together, in accordance with federal guidance for calculating poverty levels. This construct is not intended to capture household composition, which may include non-family members. Household composition is a distinct construct; if researchers wish to measure household composition, they can ask additional questions beyond the required minimum data elements.

Current place of residence
Researchers should record, at a minimum, the zip code and county of residence. These geographic indicators will allow researchers to link with other datasets to obtain area-level indicators of interest for maternal health research (e.g., location in maternity care desert).

Minimum Data Elements
Zip code
County

Data Sources and Measurement Guidance
Data are collected by self-report. There are multiple ways to record a participant's current place of residence. Any of the following approaches are recommended:

- Current address (zip code and county): Researchers may refer to the NIH-endorsed CDE here: https://cde.nlm.nih.gov/deView?tinyId=njQIyXM_By
    - *Question:* What is the (patient / participant) address?
    - *Response option:* Zip code and county.
- Current address (full residential): Researchers may use the NHANES protocol published in the PhenX toolkit: https://www.phenxtoolkit.org/protocols/view/10802
    - *Question:* Please tell me your complete physical street address.
    - *Response option:* Full address (#, Direction, Street Name, Street/Road/Avenue, Direction, PO Box, Rural Route #, City, State, Zip).

Birthplace

Minimum Data Elements
Country of birth
Notes: If within the United States, researchers also may choose to collect data on state of birth.

Data Sources and Measurement Guidance
There are multiple methods to collect participant's country of birth, including through self-report or as recorded on official records. Recommendations for collecting self-report data are provided in the PhenX protocol: https://www.phenxtoolkit.org/protocols/view/10201

- *Question:* Where were you born?
- *Response options:*
    - United States (specify state)
    - Outside of United States (specify name of foreign country or territory)
    - Prefer not to answer