Promoting Data Harmonization to Accelerate **COVID-19 Pregnancy Research**

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Healthy pregnancies. Healthy children. Healthy and optimal lives.

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Post COVID-19 Public Health Emergency Addendum

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CONTEXTUALIZING PREGNANCY COVID-19 CDEs

TRANSITION FROM PANDEMIC TO ENDEMIC COVID-19

The Public Health Emergency for COVID-19 officially expired in the United States on May 11th, 2023. This marked the transition of COVID-19 from a pandemic to endemic disease. During the three-year COVID-19 pandemic, the research community made significant achievements towards the global understanding of how COVID-19 affects maternal (pregnancy and postpartum) and neonatal health outcomes (e.g., risks of vertical transmission, transplacental antibody transfer, changes during the perinatal period through delivery etc.). In the current endemic COVID-19 phase, research on the effects of COVID-19 related to maternal and neonatal health outcomes will continue to evolve and advance our understanding of the pandemic's long-term impacts on pregnant people and neonates, with an added focus on the effects of Post-Acute Sequelae of COVID-19 (PASC), also known as Long COVID, and long-term psychosocial consequences of the pandemic.

While the common data elements (CDEs) in this report were originally designed and intended for use by researchers during the acute phase of the pandemic, many CDEs may remain applicable in future COVID-19 research. This report serves as a historical archive of CDEs for COVID-19 research in pregnant populations during the acute COVID-19 pandemic; the CDEs in this report will not be updated to an endemic COVID-19 research context. The content and tiers of these CDEs will remain as originally designed; most of them could be useful in ongoing COVID-19 studies.

USING THESE CDEs IN FUTURE COVID-19 RESEARCH

Although the research community moving forward may have different needs, priorities, and research questions than they did during the acute phase of the pandemic, we encourage researchers to incorporate these CDEs into research studies as applicable. Going forward, real-time studies of COVID-19 will have different needs than retrospective studies that research the pandemic period from 2020 – 2023.

Some CDEs are unlikely to apply in a future real-time COVID-19 study but could be used in a retrospective study with slight modification. Consider, for example, the following Psychosocial CDE:

- As a result of COVID-19 have you received…
    - Enrollment in the Special Supplemental Nutrition Program for Women, Infants, and Children, known as WIC?
        - Yes
        - No
        - Not sure
        - Decline to answer
    - One or more stimulus checks from the government?
        - Yes
        - No
        - Not sure
        - Decline to answer
    - Any amount of unemployment benefits from the government?
        - Yes
        - No

        - Not sure
        - Decline to answer

This question is unlikely to apply to future COVID-19 studies because pandemic-era government assistance policies have ended. However, this question could apply to a retrospective study by changing “have you received” to “did you receive”.

On the other hand, the following CDE in the Biomedical domain is reasonable to ask subjects in any future research study:

- Have [you/the participant] received a vaccination for COVID-19?
    - No *(if no, skip to… “if not vaccinated, why?”)*
    - Yes

This question is reasonable because the COVID-19 vaccine will continue to be available to the public and is likely to be updated seasonally. COVID-19 vaccination status is likely to be of interest in any future COVID-19 study. We encourage researchers to use their best judgment in identifying COVID-19 pregnancy CDEs that apply to their research goals and study populations.

USING THESE CDEs IN RESEARCH STUDYING FUTURE PUBLIC HEALTH EMERGENCIES

CDEs in this report may also apply to research on future public health emergencies. Measures in both the Biomedical and Psychosocial domains are likely to be of interest in any public health emergency. Many questions can be easily modified for use in a future infectious or other public health emergency by replacing the reference to SARS-CoV-2, COVID-19, or coronavirus with a reference to the new public health emergency. An example is the following CDE in the Psychosocial domain:

- How has the COVID-19 outbreak affected your regular childcare? (Mark all that apply)
    - I had difficulty arranging for childcare
    - I had to pay more for childcare
    - My spouse/partner or I had to change our work schedule to care for our children ourselves
    - My regular childcare has not been affected by the COVID-19 outbreak
    - I do not have a child in childcare

This question could be easily modified for use in a future pandemic by replacing “COVID-19 outbreak” with a different disease or exposure.

We encourage researchers to study pregnant, maternal, and neonatal populations during future health emergencies and to modify and utilize these CDEs in their research. Researchers should use their best judgment in selecting and modifying CDEs in a way that best applies to future public health emergencies in their study population. For example, given the nature of the COVID-19 pandemic, these CDEs apply well to infectious disease outbreaks, but could easily apply to other exposures with minor adaptations. For example, in the event of a major hurricane, the following modified CDE could be asked:

- Since you gave birth, has the **hurricane emergency** led to any of the following problems accessing medical care?
    - Yes
    - No

DATA HARMONIZATION AND OTHER RESOURCES

Across all biomedical research, data harmonization remains a key priority to answer complex questions about diseases and pool information on rare outcomes to improve statistical power. While this report is a historical

document that sought to accelerate COVID-19 research in pregnant, maternal, and neonatal populations in the midst of the COVID-19 pandemic, these CDEs can be applied to future COVID-19 research and research in future public health emergencies. We encourage the use of these and other CDEs to promote data harmonization in all pregnancy research. Other resources to access CDEs include the NIH CDE Repository and the PhenX Toolkit.

Promoting Data Harmonization to Accelerate **COVID-19 Pregnancy Research**

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EXECUTIVE SUMMARY

Our understanding of the highly transmissible severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that caused the COVID-19 pandemic is continuously evolving. While the global research community is working to address the impact of COVID-19, little is known about the virus' effects on pregnant women and their children. NIH-funded researchers are uniting in a data harmonization effort to recommend common biomedical and psychosocial data elements and measures that can be used across COVID-19 pregnancy studies or any study enrolling women of reproductive age. Data harmonization is a key strategy to accelerate research as it helps to inform larger, more complex questions about the effects of COVID-19 on pregnant women and their neonates and helps investigators study rare outcomes for which individual studies may be underpowered.

At the onset of the pandemic, staff at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) identified NIH-funded pregnancy cohort studies across NIH that were in various stages of development and were collecting or planning to collect data on the impact of COVID-19 on maternal and infant outcomes. NICHD invited representatives from these studies to collaborate on developing recommendations for sets of common data elements (CDEs) that could be used across the represented studies and disseminated for use by other investigative teams that conduct studies enrolling women of reproductive age, including pregnant women. The investigators who participated came from both intramural and extramural programs representing eight studies supported by two different ICs (a full list of Contributors can be found on page 4).

> *"Common data elements are critical for providing consistency in the way we collect, describe, and analyze research data. Our hope is that these common elements are central to future COVID-19 studies that enroll women of reproductive age, including pregnant women."*
>
> Diana W. Bianchi, M.D.
> NICHD Director

Herein we discuss our modified Delphi approach to develop sets of CDEs and measures (validated, where possible) through biomedical and psychosocial lenses. **Biomedical and Psychosocial Working Groups** initially identified more than 425 potential data elements categorized across 25 domains based on a research landscape analysis of available pregnancy study case report forms (CRFs), protocols, and other resources related to COVID-19 in pregnancy. **Through an iterative process, the inventory of 425 was prioritized to 64 data elements across 13 domains.**

BIOMEDICAL WORKING GROUP

Common biomedical data elements and measures aim to accelerate our understanding of the clinical course of COVID-19 and its effects on pregnant women and their neonates, which will continue to evolve as treatments and vaccines become available. The Biomedical Working Group recommended **29 CDEs across seven domains**, which included:

+ Baseline Maternal / Pregnancy Characteristics
+ Maternal COVID-19 Treatment
+ Maternal Outcomes
+ Obstetric / Pregnancy Outcomes
+ Neonatal Characteristics
+ Neonatal COVID-19 Testing
+ Early Neonatal Outcomes

Refer to the Key Findings: Biomedical Working Group for additional information.

PSYCHOSOCIAL WORKING GROUP

Common psychosocial data elements and measures aim to advance our understanding of the psychological, behavioral, and social effects of the virus and the pandemic on pregnant women and their neonates. The Psychosocial Working Group recommended a total of **35 CDEs across six domains**, including:

+ Socioeconomic Status, Housing, and Emergent Financial Strain
+ Medical Care
+ Impact on Parenting
+ Stressful Life Events
+ Maternal Mental Health
+ Health Related Behaviors

Refer to the Key Findings: Psychosocial Working Group for additional information.

Recommended CDEs and associated measures are intended for use by any planned or upcoming COVID-19 study that includes women of reproductive age or pregnant women. Recommended common data elements from our Biospecimens working group can be found in the Biospecimens Addendum. Efforts to plan for data harmonization and future combination of datasets will help to amplify the collective impact of all pregnancy studies and to better understand the unique challenges pregnant women experience during the COVID-19 pandemic. **We encourage researchers to include some or all of these measures into their studies to maximize the potential for data harmonization while continuing to advance their own study goals.** The full set of recommended measures (Appendix) is available publicly on the NIH Public Health Emergency and Disaster Research Response (DR2).

- ✓ These lists are not intended to be standalone, cohesive questionnaires. Rather, consider them building blocks to which additional study-specific elements can be added. However, CDE response options should not be deleted.
- ✓ Investigators are advised that the questions can be adapted for mode of administration by changing wording of address, e.g., “Did you…” vs. “Did the participant.”. For maximum benefit, do not substantively modify the CDE questions and responses.
- ✓ Similarly, the CDEs can be presented or arranged in any order preferred.

CONTRIBUTORS

+ International Maternal, Pediatric, Adolescent AIDS Clinical Trials **(IMPAACT)** Network
+ Pediatric HIV/AIDS Cohort Study **(PHACS)**
+ Study of Pregnancy and Neonatal health **(SPAN)**
+ Rhode Island Children's Health Equity & Development Study **(ENRICHED)**
+ Maternal-Fetal Medicine Units **(MFMU)** Network
+ HEALthy Brain and Child Development **(HBCD)**, part of The Helping to End Addiction Long-term℠ **(HEAL)** initiative
+ Global Network for Women's and Children's Health Research **(Global Network)**
+ Environmental influences on Child Health Outcomes **(ECHO)**

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CDC | Centers for Disease Control and Prevention
DIR | Division of Intramural Research - NICHD
DER | Division of Extramural Research - NICHD
DIPHR | Division of Intramural Population Health Research - NICHD
OD | Office of the Director
PRB | Perinatology Research Branch – NICHD

INTRODUCTION

Research to understand the impact of COVID-19 in pregnant and lactating women and their neonates is rapidly advancing. Our understanding of whether and how COVID-19 affects pregnancy, the risk of vertical transmission, changes during the perinatal period through delivery, and maternal and neonatal outcomes continues to evolve. At the onset of the pandemic, NICHD identified multiple NIH-supported pregnancy cohort studies in varying stages of development. Some of the identified studies were created specifically to evaluate the impacts of the virus and the pandemic on pregnant women, postpartum women, and infants, whereas others utilized pre-pandemic studies to field new surveys and data elements to address the effects of COVID-19. There are opportunities to increase the collective impact of all relevant studies by planning for data harmonization and future analyses using combined datasets. Data harmonization enables researchers to increase power for stratified analyses, including answering research questions on rare outcomes that individual studies are underpowered to address.

Collaboration across research networks and registries is critical to advancing data harmonization efforts. Representatives of NIH-funded studies participating in this collaboration include investigators from: IMPAACT, PHACS, SPAN, ENRICHED, MFMU, HBCD, Global Network, and ECHO.

NICHD assembled representatives from eight NIH-funded pregnancy studies, from both intramural and extramural programs, to develop recommendations for a set of common biomedical and psychosocial data elements and measures that, when combined across datasets, improve our collective understanding of COVID-19 in pregnant and lactating women and their neonates. These efforts complement other data harmonization efforts across the NIH. Recommended common data elements (CDEs) and associated measures are recommended for use by any planned or upcoming COVID-19 study that includes women of reproductive age or pregnant women. A two-tiered approach was used to stratify the recommended CDEs and associated measures for both biomedical and psychosocial-specific studies.

TIER 1
All COVID-19 Studies

Baseline CDEs for any study that may include pregnant women or women of reproductive age. Because around 5% of women of reproductive age are pregnant at any given point in time[1] and roughly 50% of pregnancies in the US are unplanned[2], it is important for non-pregnancy-focused studies to be prepared to collect key data specific to pregnancy when it occurs in the course of a study. Our Tier 1 recommendations provide guidance to do so.

TIER 2
Pregnancy Studies

CDEs that can be used to collect more detailed information on COVID-19 and pregnancy. Together, Tier 1 and Tier 2 comprise the baseline recommended CDEs to collect for any study focused on COVID-19 and pregnancy.

1 Ellington S, Strid P, Tong VT, et al. Characteristics of Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–June 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:769–775. DOI: http://dx.doi.org/10.15585/mmwr.mm6925a1

2 Finer LB, Zolna MR. N Engl J Med. 2016 Mar 3;374(9):843-52. DOI: 10.1056/NEJMsa1506575.

APPROACH

Three working groups (Biomedical, Psychosocial, and Biospecimens) were established with representatives from intramural and extramural NIH-funded pregnancy cohort studies: ECHO, SPAN, the HBCD study (NIH HEAL Initiative), IMPAACT, ENRICHED, Global Network, MFMU, and PHACS. Recommended common data elements from our Biospecimens working group can be found in the Biospecimens Addendum. Through a series of approximately eight to twelve meetings each, a modified Delphi approach was used to **1) understand the landscape of current and planned COVID-19 research in pregnant women, 2) define key scientific questions, 3) prioritize CDEs to address key research questions, and 4) define recommended common measures using validated measures when possible.** The group members:

CONDUCT LANDSCAPE ANALYSIS

- Collected available CRFs, instruments, and protocols from each of the eight studies to better understand the landscape of current and planned NIH-funded COVID-19 research in pregnant women.
- Reviewed publicly available instruments from sites such as DR2 and PhenX, including validated measures, to understand the broader COVID-19 in pregnancy and general COVID-19 research landscape.
- Assessed existing literature about the effect of COVID-19 on pregnant women to inform later prioritization and research categories.

DEFINE KEY SCIENTIFIC QUESTIONS

- Reviewed existing literature on multidisciplinary research priorities to understand gaps and create an initial list of scientific questions regarding the effects of COVID-19 on pregnant and lactating women and their neonates in the context of psychosocial effects, biomedical data, and biospecimen collection and analysis.
- Prioritized key scientific questions through a series of discussions based on working group member expertise, experience in the field, participation in planning extramural COVID-19 and pregnancy studies, and understanding of the current COVID-19 in pregnancy research landscape. The final lists of key scientific questions that drove both the biomedical and psychosocial recommendations can be found in the Appendix.

PRIORITIZE DATA ELEMENTS

- Created inventories of data elements (spreadsheet) based on landscape analyses and identified commonalities and gaps across studies in the field, as well as across the biomedical and psychosocial inventories.
- Excluded standard demographic information (e.g., participant age, race / ethnicity) as well as a small set of COVID-19 specific data elements expected to be collected by all COVID-19 studies (e.g., participant COVID-19 diagnosis, date of test) to ensure our final recommendations provide added value and are not duplicative.
- Categorized the data elements into domains, such as “Maternal Outcomes” and other research topics.
- Prioritized domains and common data elements through an iterative, modified Delphi approach to identify the top ~50 data elements per working group.
- Stratified common data elements into two tiers and further prioritized CDEs within each tier. Tier 1 is recommended as a baseline applicable to any study that may include pregnant women or women of reproductive age; Tier 2 CDEs, in conjunction with the CDEs represented in Tier 1, serve as a baseline recommendation for any study focused on COVID-19 and pregnancy.

DEFINE DATA MEASURES

- Identified potential measures for each Tier 1 and Tier 2 data element based on CRFs, questionnaires collected as a part of the landscape analysis, and relevant validated measures from other non-COVID and non-pregnancy specific studies.
- Prioritized measures through several rounds of review to identify recommended measures for each Tier 1 and Tier 2 data element. In doing so, we adopted a hierarchical approach, with top preference for 1) known, validated instruments, followed by 2) measures from COVID-19 studies already in the field, 3) modified versions of existing measures, and 4) measures developed by our working group(s)
- Tested the compilation of recommended measures to understand cohesion and participant burden (i.e., time needed to complete the questionnaire) and refined as needed.

KEY FINDINGS

The summary below provides details on the number of domains and CDEs prioritized by the Biomedical and Psychosocial Working Groups. More detailed findings are highlighted in the following sections.

IN SUMMARY

425+ Data elements identified across Biomedical and Psychosocial Working Groups

Began to prioritized data elements organized by domain

13 Domains identified across Biomedical and Psychosocial Working Groups

Iteratively prioritized data elements into two tiers and narrowed to final recommended CDEs and measures

64 Prioritized data elements

Biomedical	Psychosocial
- **21** Tier 1	- **22** Tier 1
- **8** Tier 2	- **13** Tier 2

Biomedical

Baseline Maternal / Pregnancy Characteristics
Maternal COVID-19 Treatment
Maternal Outcomes
Obstetric / Pregnancy Outcomes
Neonatal Characteristics
Neonatal COVID-19 Testing
Early Neonatal Outcomes

Psychosocial

Socioeconomic Status, Housing, and Emergent Financial Strain
Medical Care
Impact on Parenting
Stressful Life Events
Maternal Mental Health
Health Related Behaviors

KEY FINDINGS: BIOMEDICAL WORKING GROUP

The Biomedical Working Group set out to create a set of CDEs that would collectively help researchers understand the clinical course of the disease and its effects on pregnant women and their neonates (e.g., maternal and neonatal outcomes). Given known discrepancies in testing, personal protective equipment (PPE), and safety precautions across institutions, researchers across studies should plan to collect information using the same measures and methods whenever possible to augment data harmonization. Building from a baseline set of data elements expected to be collected by all COVID-19 studies (e.g., COVID-19 symptoms, test results, and date of diagnostic test), the Biomedical Working Group prioritized a total of 29 CDEs to be gathered via medical chart abstraction or downloaded data from electronic health records. Recommendations assume that information from all patient visits (e.g., prenatal visits, COVID-19 testing, and delivery) can be collected.

We encourage researchers to update these recommended measures as needed to reflect new treatments, support systems, and vaccines as they become available. We also encourage researchers to thoughtfully consider including both vaccinated and non-vaccinated pregnant women in their studies when vaccines become available.

SUMMARY OF RECOMMENDATIONS

The Biomedical Working Group prioritized seven total domains (bolded below) to guide recommendations. Each domain is made up of between two and eleven individual CDEs. The summaries below describe why each domain was chosen and why their underlying CDEs are important to better understanding the effects of COVID-19 on pregnant and lactating women and their neonates.

- **Baseline Maternal / Pregnancy Characteristics:** This domain, which collects information on current and past pregnancies, gives researchers an opportunity to delineate between health effects that may result from COVID-19 and those that may result from prior risk factors.
- **Maternal COVID-19 Treatment:** As our understanding of COVID-19 evolves and new treatments become available, it is crucial to track how pregnant women respond to various interventions. Logging treatment and interventions allows researchers to do so.
- **Maternal Outcomes:** Collecting and measuring maternal outcomes, such as delivery route and maternal complications during labor, are critical to analyzing how COVID-19 may be affecting women throughout pregnancy, labor, and delivery, including obstetric management throughout.
- **Obstetric / Pregnancy Outcomes:** Similarly, it is important to log pregnancy outcomes like congenital malformations and clinical chorioamnionitis to determine if adverse outcomes occur more frequently or differentially amongst pregnant women infected with COVID-19.
- **Neonatal Characteristics:** Keeping a record of baseline neonatal characteristics will help to determine how COVID-19 may influence neonatal size or how neonatal outcomes may differ between sexes.
- **Neonatal COVID-19 Testing:** Test results and testing mechanisms are a vital part of helping researchers define and understand mother to baby and in-hospital transmission, which is crucial to our broader understanding of the virus.
- **Early Neonatal Outcomes:** This domain aims to capture neonatal outcomes specifically related to infection, ICU admissions, morbidity, and mortality during delivery hospitalization to inform our understanding of the risks of maternal or neonatal COVID-19 positivity to neonates.

The Final Biomedical CDE recommendations, organized by domain, are listed below. Items without asterisks represent Tier 1 CDEs; items with asterisks represent Tier 2 CDEs. The recommended measures associated with each of these CDEs can be found in the Appendix: COVID-19 Pregnancy Registry | Biomedical Recommended Measures.

BASELINE MATERNAL / PREGNANCY CHARACTERISTICS

Estimated Due Date
Date of Delivery / End of Pregnancy
Maternal Height and Weight
Pregnancy History*
Pre-Pregnancy Conditions*
COVID-19 Vaccination History*
Flu Vaccination History*

MATERNAL COVID-19 TREATMENT

Was the Participant Hospitalized due to COVID-19?
Indication for Hospitalization
Was The Participant in the ICU due to COVID-19?
COVID-19 Treatment Medication
Highest Level of Respiratory Support for COVID-19

MATERNAL OUTCOMES

Delivery Route
Maternal Complications
Onset of Labor*

OBSTETRIC / PREGNANCY OUTCOMES

Major Congenital Malformation
Clinical Chorioamnionitis*

NEONATAL CHARACTERISTICS

Sex
Birth weight
Length
Head circumference*

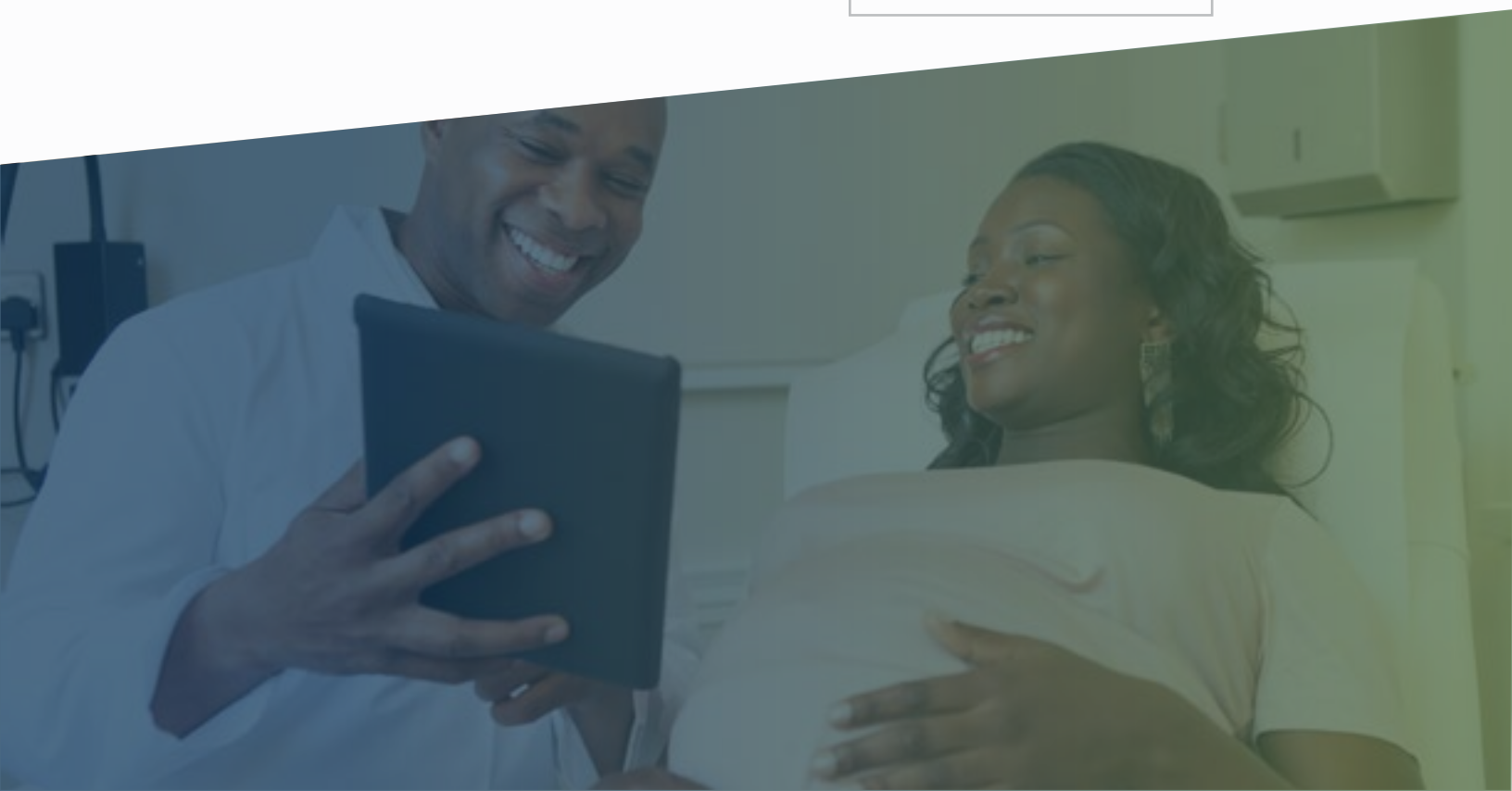
NEONATAL COVID-19 TESTING

COVID-19 Test Result
Date(s) of Testing
Type of Test*

EARLY NEONATAL OUTCOMES

Highest Level of Care Required
Respiratory Support
Neonatal Morbidities
Final Status of Infant
Antiviral Medications

TIER 1
TIER 2*



KEY FINDINGS: PSYCHOSOCIAL WORKING GROUP

The Psychosocial group aimed to create a set of CDEs that would collectively help researchers understand the psychological, behavioral, and socioeconomic effects of the pandemic on pregnant women and their neonates. Pregnant mothers are uniquely and acutely affected by many of the changes caused by the pandemic, like enforced social distancing in the delivery room, loss of health care coverage, and more. The recommendations herein focus specifically on this intersection of pandemic effects.

The Psychosocial Working Group solicited a literature review from the NIH library early in the process of data harmonization planning efforts to better understand the existing research landscape on the psychosocial effects of COVID-19 on pregnant women and to identify research gaps to better inform our recommendations. At the time of this review (September 2020), research on the psychosocial effects of the COVID-19 pandemic (as well as SARS, ZIKA, and other infectious diseases) on pregnant women was still very limited. The group therefore relied more heavily on working group member expertise, experience in the field, participation in planning extramural COVID-19 and pregnancy studies and, understanding of the current COVID-19 in pregnant research landscape. In contrast to the biomedical CDE recommendations, the majority of psychosocial CDEs require interviews or surveys directly with research participants. In total, survey collection of all of our selected measures is expected to take approximately 20 minutes.

SUMMARY OF RECOMMENDATIONS

The Psychosocial working group prioritized six total domains (bolded below) to guide recommendations. Each domain is made up of between two and eleven individual common data elements relevant to that category. The summaries below describe why each domain was chosen and why their underlying CDEs are important to better understanding the effects of COVID-19 on pregnant and lactating women and their neonates.

- **Socioeconomic Status, Housing, and Emergent Financial Strain:** Many social determinants of health (e.g., financial and job security, social interaction, etc.) have been greatly affected as a result of the pandemic. This domain helps researchers to understand how a change in socioeconomic factors may be affecting the health of pregnant and lactating women and their neonates.
- **Medical Care:** This domain seeks to understand how pandemic-related safety restrictions, changes in models of care, and personal preferences have affected mothers' abilities to receive medical care throughout pregnancy.
- **Impact on Parenting:** This domain aims to measure how the pandemic may be affecting the maternal-infant relationship through feelings of attachment and breastfeeding and how disruptions in childcare or education for a mother's other children may affect the mother-baby dyad's psychosocial well-being.
- **Stressful Life Events:** The social effects of the pandemic and social distancing likely have exacerbated stressful life events like discrimination and intimate partner violence in the general population. Related data elements enable researchers to better understand how that trend is or is not reflected in the lives of pregnant women.
- **Maternal Mental Health:** Current evidence suggests that rates of mood disorders and anxiety have increased in the general population during the pandemic. This domain helps researchers to quantify the effect of pandemic-related stressors on mothers' mental health and wellbeing, helping to inform observed maternal and neonatal outcomes.
- **Health Related Behaviors:** Pandemic-related stress has driven many to engage in riskier health behaviors like increased substance use. It is important to study the health behaviors of pregnant women during the pandemic, as they may be associated with maternal and neonatal outcomes.

The Final Psychosocial CDE recommendations, organized by domain, are listed below. Items without asterisks represent Tier 1 CDEs; items with asterisks represent Tier 2 CDEs. The recommended measures associated with each of these CDEs can be found in the Appendix: COVID-19 Pregnancy Registry | Psychosocial Recommended Measures.

SOCIOECONOMIC STATUS, HOUSING, AND EMERGENT FINANCIAL STRAIN

Education Level
Financial Strain / Material Hardship
Household Income
Government Assistance
Loss / Change of Housing
Food Security
Current Employment
Changes in Employment Situation
COVID-19 Exposure due to Occupation
Zip Code
Household Crowding*

MEDICAL CARE

Health Insurance Status
Access to Medical Care
Changes to Health Insurance*
Distress About Access to Medical Care*
Changes to Delivery Plan due to COVID-19*
Distress About Changes to Delivery Plan*

STRESSFUL LIFE EVENTS

Racial / Ethnic Harassment and Discrimination
Intimate Partner Violence
Change in Frequency of Abuse*

IMPACT ON PARENTING

Breastfeeding
Feelings of Attachment to Newborn
Impact of Pandemic on Childcare
Impact of Pandemic on Children's Education*
Distress About Impact of Pandemic on Children's Education*
Distress About Impact of Pandemic on Childcare*

MATERNAL MENTAL HEALTH

Antepartum / Postpartum Depression
COVID-19 Related Anxiety
Generalized Anxiety Disorder Symptoms
Coping Mechanisms
Sources of Support
Loneliness / Social Isolation*

HEALTH RELATED BEHAVIORS

Pre-Pregnancy and Current Alcohol Use
Current Opioid Use
Current Weekday Hours of Sleep

TIER 1
TIER 2*

CONCLUSION & NEXT STEPS

As the COVID-19 pandemic continues to affect our society, researchers have been pushed to advance our understanding of the virus on a rapid timeline. As research continues, it is important to plan for data harmonization across studies so that the efforts of each individual study can contribute to a larger, more impactful collective body of research. Specifically, data harmonization will provide greater power to study rare outcomes when studies with smaller sample sizes are combined. The recommendations herein can aid in the data harmonization planning process. Our recommendations can be especially helpful for researchers who may not be accustomed to researching pregnancy specifically, but whose COVID-19 studies include women of reproductive age who may become pregnant throughout the course of study. In this scenario, we hope that Tier 1 recommendations provide important, easily incorporated measures.

In line with the NIH COVID-19 strategy[3], which promotes collaborative science to address the unprecedented health challenge of the COVID-19 pandemic, we have made our recommendations available on the NIH Public Health Emergency and Disaster Research Response (DR2). We encourage researchers from planned and ongoing studies to incorporate our recommendations into their studies where possible to help streamline and harmonize data for sharing most effectively. Finally, we recommend that all investigators continuously update these CDEs and measures to reflect the most current research as our understanding of COVID-19 and its treatments progress.

3 NIH-Wide Strategic Plan for COVID-19 Research July 2020: https://www.nih.gov/research-training/medical-research-initiatives/nih-wide-strategic-plan-covid-19-research

Biospecimens Working Group Addendum

INTRODUCTION AND KEY FINDINGS: Biospecimens Working Group

Collecting and analyzing biospecimens (e.g., maternal blood, cord blood, placenta, breastmilk etc.) can help to illuminate the effects of COVID-19 on maternal and child health, identify biomarkers, assess vertical transmission, and inform future treatment and vaccination strategies. Given the global pandemic and growing body of research on COVID-19 in pregnant and lactating women, the collective impact of pregnancy studies and any study enrolling women of reproductive age can be amplified by planning for future analyses using combined datasets. Data harmonization will be especially helpful to address more complex questions about the effects of COVID-19 on pregnant and lactating women and their neonates and will help investigators to study rare outcomes for which individual studies may be underpowered.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) convened researchers across several NIH-funded pregnancy cohort studies to recommend considerations for biospecimen data harmonization. These recommendations build from previous efforts to recommend biomedical and psychosocial common data elements (CDEs) for researchers studying COVID-19 in pregnancy or any study enrolling women of reproductive age. The Biospecimens Working Group used a modified Delphi approach to prioritize specimens and methodologies for collection and storage. **The working group identified maternal blood, cord blood, placenta, and breastmilk as the key specimens important to advanced research of COVID-19 in pregnant and lactating women.**

Considerations for collection, timing (e.g., at time of delivery, at time of acute infection, at various times in gestation), storage, and examples of analyses are provided in the tables below. Collectively, these recommendations aim to provide investigators with guidance on standardized collection and storage methodologies which allow for an array of analyses that could be performed.

SUMMARY OF RECOMMENDATIONS

COVID-19 studies in pregnant and lactating women or any study enrolling women of reproductive age and collecting biospecimens each have their own unique research questions, protocols, and analysis strategies. Given this diversity, our recommendations are broken into three Tiers. The recommended biospecimen, collection method, timing, storage, and representative analysis become increasingly more time and resource intensive as well as increasingly specialized with each successive Tier. Researchers should choose their specimen(s) of interest based on their study's goals and subsequently choose methods for collecting, storing, and analyzing their selected specimen(s) from the Tier most appropriate for their study and resource constraints.

Tier 1: Collection, processing, and storage are less intensive and do not require specialized processing.
Tier 2: Collection, storage, and processing may become more complex to accommodate more specialized analyses. These collection methods also allow for a wider array of possible analyses.
Tier 3: Specialized collection, processing, and / or storage methods that allow for even more specialized analyses compared to Tiers 1 and 2.

An overarching recommendation is that the delivered placenta from any participant who had been diagnosed with COVID-19 during pregnancy (whether at the time of delivery or before) should be submitted for pathologic examination as an integral part of clinical care.

If a perinatal pathologist is available, we recommend that the placenta be sent for further review.

If a perinatal pathologist is not available, the placenta can be sent to pathology and evaluated using the Amsterdam criteria[4] for sampling and diagnosis.

The following tables outline recommendations for biospecimen samples to be collected by investigators studying COVID-19 in a population that includes women of reproductive age, and specifically pregnant and lactating women. Our working group specifically focused on four main specimens relevant to this population and area of study: maternal blood, cord blood, placenta, and breastmilk / colostrum. Considerations for collecting, processing, and analyzing maternal respiratory specimens are also included.

Both maternal and cord blood allow researchers to evaluate viral load, perform cellular fraction, and identify certain inflammatory markers which all serve to help researchers understand disease severity and associated symptoms. Additionally, maternal and cord blood can be used for genotyping to understand potential genetic factors in varied reactions to SARS-CoV-2. **Collecting the placenta for evaluation is especially important because placental evaluation is clinically indicated for all women with COVID-19 in pregnancy.** Placental samples can specifically be used to understand placental infection and potential vertical transmission. **If a perinatal pathologist is available, we recommend that the placenta be sent for further review. If a perinatal pathologist is not available, the placenta can be sent to pathology and evaluated using the Amsterdam criteria[4] for sampling and diagnosis.** The placenta should be recovered as soon as possible (1-2 hours maximum) after delivery and can be stored in a refrigerator (4ºC) until fixation or transfer to the lab. Finally, breastmilk can also help researchers to evaluate viral load, perform cellular fraction, and can be used for sequencing, helping researchers to understand disease severity and potential vertical transmission.

4 Khong TY, Mooney EE, Ariel I, Balmus NC, Boyd TK, Brundler MA, et al. Sampling and Definitions of Placental Lesions: Amsterdam Placental Workshop Group Consensus Statement. Arch Pathol Lab Med 2016;140:698-713.

The table below highlights key considerations for collection, timing, storage, and representative examples of analyses that can be performed for each specimen, organized by Tier. Footnotes are used throughout the tables to highlight important nuances and additional considerations for specimen collection, processing, and analysis.

TIER 1 BIOSPECIMENS				
Specimen	**Collection**	**Timing**	**Storage**	**Sample Analyses**
Maternal Blood[5]	• **Plasma / Buffy Coat:** EDTA tubes (at least 10mL total) • **Serum:** Serum separator (5mL)	• At time of acute illness and / or • At delivery	• **Plasma:** Freeze in 200 µL (max 1 mL) aliquots, store at -80ºC • **Serum:** Freeze in200 µL (max 1 mL) aliquots, store at -80ºC • **Buffy coat:** Freeze, store at -80ºC	**Plasma / Serum:** SARS-CoV-2 RNA viral load SARS-CoV-2 antibodies (IgG, IgA, neutralizing antibody evaluation) Cytokine analysis **Buffy coat:** Analysis of cellular fraction (Evaluation of properties of specific cellular fractions such as T-cells, monocytes)
Cord Blood	• **Plasma / Buffy Coat:** EDTA tubes (at least 10-15 mL total, may be less for pre-term deliveries) • **Serum:** Serum separator (7.5mL)	At delivery	• **Plasma:** Freeze in 200 µL (max 1 mL) aliquots, store at -80ºC • **Serum:** Freeze in 200 µL (max 1 mL) aliquots, store at -80ºC • **Buffy coat:** Freeze, store at -80ºC	**Plasma / Serum:** SARS-CoV-2 RNA viral load SARS-CoV-2 antibodies (IgG, IgA, neutralizing antibody evaluation) Cytokine analysis **Buffy coat:** Analysis of cellular fraction (Evaluation of properties of specific cellular fractions such as T-cells, monocytes)
Placenta	Fixed tissue	At delivery	Store at 4ºC until fixation Once fixed, can be stored as formalin-fixed paraffin embedded blocks	RNA *in situ* hybridization (RNA-ISH)
	Maternal side biopsy and Fetal side biopsy	As soon as possible; within 1-2 hours of delivery maximum (RNA will degrade)	Process in RNAlater, following manufacturer instructions Store preserved tissue at -80ºC (or -20ºC if 80ºC not available)	SARS-CoV-2 RNA analyses[6]
Colostrum and/or mature milk	Pump into colostrum cup or Hand expression into colostrum cup For larger volume: Pump into pumping containers or storage containers	• During delivery admission or • At postpartum visit	• **Small volume:** Aliquot (e.g. 1 mL aliquots) and store at –80ºC • **Large volume** (e.g. 10 mL or above): Spin and separate cellular fraction and supernatant. Aliquot (e.g. 1 mL aliquots) and store at –80ºC	• SARS-CoV-2 RNA viral load[7] • SARS-CoV-2 antibodies (IgG, IgA, neutralizing antibody evaluation)

[5] Blood draws for research in pregnancy should not exceed 50 mL in 8 weeks. Those with Hct < 24 should not provide blood for research

[6] Preservation in RNAlater permits both RNA and DNA analyses

[7] Specific guidance to participants and adherence to breast cleaning protocols is critically important if breastmilk viral load quantification is planned

TIER 2 BIOSPECIMENS

Specimen	Collection	Timing	Storage	Sample Analyses
Maternal Respiratory Specimens[8]	• Nasopharyngeal swab (preferred) • Nasal swab • Oropharyngeal swab (RTq-PCR) • Saliva vial / cup	• 11-14 weeks[9] • 18-22 weeks[8] • 28-32 weeks[8] • Delivery • At time of acute illness (if applicable)[10]	• **Swab:** Swirl in PBS, aliquot PBS and freeze at -80ºC • *If diagnostic swab can be retrieved from clinical lab, it can be used for quantitative (viral load) and other assays* • **Saliva:** Process with DTT, store at -80C	Use to confirm SARS-CoV-2 negative status in control group SARS-CoV-2 RNA viral load
Maternal Blood[4]	• **Plasma, Buffy Coat, and/or PBMC:** EDTA tubes (at least 10mL total) • **Serum:** Serum separator (5mL)	• 11-14 weeks[8] • 18-22 weeks[8] • 28-32 weeks[8] • Delivery • At time of acute illness	• **Plasma:** Freeze in 200 µL (max 1 mL) aliquots, store at -80ºC • **Serum:** Freeze in 200 µL (max 1 mL) aliquots, store at -80ºC • **Buffy coat:** Freeze, store at -80ºC • **PBMC:** Store in freezing media in liquid nitrogen (LN_2)	• Inflammatory markers (e.g. IL-6, TNF-a, IL-1B, IFN-g, IL-10, CRP/ESR) • T-cell, monocyte, other specific cell fraction experiments (EDTA only) • AM cortisol or CRH
	PaxGene tube (2.5 or 5 mL)	• 11-14 weeks[8] • 18-22 weeks[8] • 28-32 weeks[8] • Delivery • At time of acute illness	• Shake vigorously • May keep at room temp for 2-24 hrs • Freeze whole tube, store at -80ºC	Transcriptomic/global gene expression analyses
Cord Blood	**For PBMC:** EDTA tubes (at least 10-15 mL total)	At delivery	**Isolated PBMC:** Store in liquid nitrogen (LN2)	**PBMC:** • Analysis of cellular fraction (scRNA-Seq, evaluation of properties of specific cellular fractions such as T-cells, monocytes) • Genotyping (array-based)
	PaxGene tube (2.5 or 5 mL)	At delivery	• Shake vigorously • Keep at room temp for 2-24 hrs • Freeze whole, store at -80ºC	Transcriptomic/global gene expression analyses
Placenta	• Maternal side placental biopsy and • Fetal side placental biopsy	As soon as possible; within 1-2 hours of delivery maximum (RNA will degrade)	• Process in RNAlater, following manufacturer instructions • Store preserved tissue at -80ºC	• SARS-CoV-2 RNA viral load • RNA RTq-PCR for specific genes of interest • DNA methylation analyses • Genotyping (array-based)
	• Full thickness biopsies or • Remaining whole placenta	• Take biopsies in pathology lab	• Formalin-fixed, paraffin-embedded blocks • Fixed tissue can be sectioned and stored on slides and in in paraffin-embedded blocks	• RNA *in situ* hybridization (RNA-ISH) to define placental infection • ACE2/TMPRSS2 protein expression patterns
Breastmilk	• **Large volume:** Pump into pumping containers or storage containers	• At delivery and/or • Post-partum	• **Large volume** (e.g. 10 mL or above): Spin and separate cellular fraction and supernatant	**Cellular fraction of breastmilk:** • Sequencing • Isolation of T-cells, NK cells, and antibody-producing B cells

8 Respiratory specimens only necessary to be collected to document COVID-19 negative status at the time of collection if the participant provides other samples for study

9 Can alternatively collect at 1st, 2nd, 3rd trimester appointments. Ideally, align maternal respiratory specimens collection with maternal blood draw

10 If a participant that was previously designated as a control becomes ill with COVID-19, specimens collected after that point can no longer be used as a control

TIER 3 BIOSPECIMENS

Specimen	Collection	Timing	Storage	Sample Analyses
Saliva (Tier 3)	Oragene	Follow time restrictions included in instructions	• Process with DTT • Store at -80ºC	Genotyping
Placenta	• Maternal biopsy and • Fetal side biopsy	As soon as possible; within 1-2 hours of delivery maximum (RNA will degrade)	• Snap freeze tissue in liquid nitrogen (preferred) or on dry ice • Store at -80ºC	• Protein isolation • Single-cell RNA-seq • DNA/RNA extraction
	• Full thickness biopsies or • Remaining whole placenta	Take biopsies in pathology lab	• Formalin-fixed, paraffin-embedded blocks • Fixed tissue can be sectioned and stored on slides and in in paraffin-embedded blocks	CD147 & CD26 protein expression patterns
	Membrane or decidua basalis	As soon as possible Within 1-2 hours of delivery maximum (RNA will degrade)	Process fresh for cell isolation per protocol	Inflammatory/immune analyses (e.g., FACS, flow cytometry, transcriptomics, pro-inflammatory cytokine quantification)

Psychosocial and Biomedical Appendix

A1. Biomedical Prioritized Key Scientific Questions

Natural history of COVID-19 in pregnancy and pregnancy complications or outcomes

1. Estimate the hospitalization and ICU admission rates in pregnant women with COVID-19.
2. Estimate the case fatality rate among pregnant and postpartum women with COVID-19.
3. Describe the prevalence of adverse pregnancy outcomes (including pregnancy loss) among women with COVID-19.
4. Describe adverse pregnancy outcomes and identify risk factors.
5. Describe the racial / ethnic disparities associated with COVID-19 in pregnant women

Neonatal COVID-19 status

6. Estimate the risk of vertical transmission of COVID-19.
7. Estimate the incidence of congenital anomalies in newborns born to pregnant women infected with COVID-19.
8. Estimate the neonatal morbidity/mortality outcomes among pregnant women infected with COVID-19.
9. Understand the impact of COVID-19 treatment in pregnancy on maternal and infant outcomes mother and infant.

A2. Biomedical Recommended Measures

COVID-19 Pregnancy Registry | Biomedical Recommended Measures

The recommendations herein were largely adapted from the Maternal Fetal Medicine Unit (GRAVID)COVID-19 and Delivery Case Report Forms with additional input from the Study of Pregnancy and Neonatal Health (SPAN) and other ongoing or planned studies.

A subset of measures included here are designated as "Tier 2." Those without this designation—i.e., "Tier 1" measures—are recommended for all studies that may include women of reproductive age and pregnant women. Tier 2 measures are suggested additional measures for studies focused exclusively onCOVID-19 in pregnancy and/or for any study interested in taking a "deeper dive" in certain domains.

Note: Elements written in blue were added/updated by WG on July 2021.

Domain: Baseline Maternal / Pregnancy Characteristics

Estimated Due Date
- Month/Day/Year

Date of Delivery / End of Pregnancy
- Month/Day/Year

Maternal Height and Weight
- Height in meters
- Weight in kilograms

Pregnancy History (Tier 2)
- Mark the number of previous pregnancies for which the patient has experienced the following outcomes [Drop-down selection [0, 1, 2, 3, 4, 5 or more]:
    - Live Birth
    - Miscarriage [<20 weeks]
    - Stillbirth [20+ weeks]
    - Preterm delivery (<37 weeks)
        - Was the preterm delivery spontaneous? [Yes / No]
            - If no, then select indication for indicated preterm birth:
                - COVID-19
                - Maternal indication
                - Fetal indication
                - Other
- Mark Yes/No/Unknown for each of the following pregnancy / obstetric complications during previous pregnancies:
    - Gestational hypertension
    - Preeclampsia
    - Gestational diabetes
    - Prior cesarean

Pre-pregnancy conditions (Tier 2)
- Mark Yes/No/Unknown to denote if the patient has any of the following pre-pregnancy conditions for the current pregnancy:

- Pregestational diabetes
- Hypertension
- Pulmonary disease
- Immune suppression (includes HIV?)
- HIV
- VTE/PE
- Mood Disorder (Depression / MDD, Bipolar Disorder)
- Anxiety / Panic Disorder
- PTSD

COVID-19 vaccination history (Tier 2)

- Have [you/the participant] received a vaccination for COVID-19?
  - No *(If no, skip to…"if not vaccinated, why?")*
  - Yes
- Have [you/the participant] completed the vaccination for COVID-19 (dose or doses)?
  - No *(If no, skip to…"if not vaccinated, why?")*
  - Yes
    - ***If yes,*** on what date did the patient receive the first dose of vaccine?
      - Month/Day/Year
    - ***If yes,*** on what date did the patient receive the second dose of vaccine?
      - Month/Day/Year
      - N/A
    - Enter the name of the vaccine (if known)? [4]
      - AstraZeneca's COVID-19 vaccine
      - Janssen's (Johnson & Johnson) COVID-19 vaccine
      - Moderna's COVID-19 vaccine
      - Novavax's COVID-19 vaccine
      - Pfizer's COVID-19 vaccine
      - Other, Specify
    - [Tier 2] Did [you/the participant] receive a COVID-19 vaccine 90 days after treatment with monoclonal antibodies or 30 days after an active COVID-19 infection?
      - No
      - Yes
      - Unknown
      - Prefer not to answer
  - Did you experience any side effects within 2 weeks after the **FIRST** vaccine dose?[5]
      - No
      - Yes
      - I do not know
    - If yes, what side effect(s) did you experience? Select all that apply.
      - Pain where shot was given
      - Fever ≥100.4F

[4] Project 5 Draft CDEs/FDA

[5] DR2 Vaccine Questions

        - Fatigue/tiredness
        - Headache
        - Muscle pain in parts of your body beyond where shot was given
        - Immediate, severe allergic reaction (including difficulty breathing and feeling faint, nausea and/or vomiting)
        - Skin rash
        - Facial swelling
        - Other (please describe)
    - Did you experience any side effects within 2 weeks after the **SECOND** vaccine dose [if applicable]?
        - No
        - Yes
        - I do not know
        - If yes, what side effect(s) did you experience? Select all that apply.
            - Pain where shot was given
            - Fever ≥100.4F
            - Fatigue/tiredness
            - Headache
            - Muscle pain in parts of your body beyond where shot was given
            - Immediate, severe allergic reaction (including difficulty breathing and feeling faint,
            - nausea and/or vomiting)
            - Skin rash
            - Facial swelling
            - Other (please describe)
    - [Tier 2] Medications to treat symptoms post-vaccine
        - Ibuprofen
        - Acetaminophen
        - Aspirin
        - Antihistamines
        - Other, specify:_____
- If not vaccinated, Why? (Select ONE best reason)
    - The vaccine is not available to me
    - Doctor did not recommend it
    - My family did not want me to take it
    - It was not well tested in ethnically diverse people
    - It was not well tested among pregnant individuals
    - I cannot afford the vaccine
    - I have not had time to get it
    - I'm at low risk and do not need it
    - It is riskier to go get the vaccine than staying at home
    - Worried about side effects
    - The vaccine's technology hasn't been tested enough
    - Vaccine was approved too fast

        - No long-term safety data available
        - Concerned about vaccine storage
        - Already had COVID-19
        - Other, specify:_____
- Do you intend to receive a coronavirus (COVID-19) vaccine?[6]
    - I intend to get it as soon as possible
    - I intend to wait to see how it affects others in the community before I get it
    - I do not intend on getting it soon, but might sometime in the future
    - I do not intend to ever get the vaccine
- [Tier 2] Is there anything that might convince you to change your mind about getting vaccinated? (Based on those who would definitely not get the COVID-19 vaccine)[7]
    - No/Nothing
    - More research
    - If it were mandatory/required
    - Other
    - Don't know

Flu vaccination history (Tier 2)

- Has the patient received a vaccination for influenza during this season/year?
    - Yes / No/ Unknown
        - ***If yes,*** on what date did the patient receive the vaccine?
            - Month/Day/Year

Domain: Maternal COVID-19 Treatment

- Was the participant hospitalized for COVID-19 in this pregnancy or while pregnant?
    - Yes / No

Indication for Hospitalization

[Drop down, select 1 and answer appropriate follow up questions]

- What was the indication for the patient's hospitalization?
    - Admitted due to COVID-19 ***[If selected, select one below]***
        - Did not result in delivery
        - Delivered (include if pregnancy loss)
            - Spontaneous labor
            - Induced
            - No labor
    - Admitted for delivery (spontaneous labor, induction, CD)
        - Yes / No
            - If yes, SARS-CoV-2 test performed?
                - Yes, positive
                - Yes, negative

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[6] DR2 Vaccine Questions

[7] Kaiser Family Foundation COVID-19 Vaccine Monitor

- Yes, missing
- No
- Unknown
    - If yes, positive: Was the patient symptomatic?
        - Yes
        - No
- Admitted for non-COVID / non-labor and delivery
    - Did the patient test positive for SARS-CoV-2?
    - Did the admission result in delivery / end of pregnancy?
- Date admitted
    - Month/Day/Year

Was the Participant in the ICU due to COVID-19?

- Yes / No
- Date admitted
    - Month/Day/Year

COVID-19 Treatment Medication

- Mark Yes/ No/ Unknown to denote if the patient received any of the following COVID-19 treatments
- *Please note that these options reflect the available treatments in October 2020. Please expand this list as necessary as treatment regiments evolve*
    - Oseltamivir
    - Hydroxychloroquine / chloroquine therapy
    - Remdesivir
    - Azithromycin
    - Convalescent plasma
    - Other antiviral
    - Unfractionated heparin
    - Low molecular weight heparin
    - Tocilizumab
    - Bevacizumab
    - Eculizumab
    - Ruxolitinib
    - Dexamethasone
    - Methylprednisolone
    - Hydrocortisone IV / injection
    - Other immune modulator
    - Other corticosteroid
    - Other (please specify)

Highest Level of Respiratory Support for COVID-19

[Select one]

- None
- Blow-by
- Oxygen by cannula / oxyhood / mask
- High flow nasal cannula

- Continuous positive airway pressure
- Bilevel positive airway pressure
- Ventilation

Domain: Maternal Outcomes

Delivery Route

[Select one]

- Vaginal – non-operative
- Vaginal – operative
- Pre-labor cesarean / cesarean without labor
- Intrapartum cesarean
    - ***If cesarean***, indication for cesarean *(Tier 2)* [Select multiple]
        - COVID-19
        - Maternal indication
        - Fetal indication
        - Other

Onset of Labor (Tier 2)

[Select one]

- No labor
- Spontaneous
- Spontaneous, augmented
- Induced
    - Primary indication for induction
        - COVID-19 infection
        - Hypertension / preeclampsia
        - IUGR
        - Non-reassuring fetal status
        - PROM
        - IUFD/ Stillbirth
        - Congenital malformations / fetal anomaly
        - Oligohydramnios
        - Abruption
        - Chorioamnionitis
        - Elective
        - Cholestasis
        - Polyhydramnios
        - Diabetes / Macrosomia
        - Other maternal medical complications
        - Post term (>=41 weeks)

Maternal Complications

[Select all that apply]

- Cerebral venous sinus thrombosis
- Renal failure requiring dialysis
- Arterial thrombosis cerebrovascular accident (CVA)

- Cardiomyopathy
- Pulmonary embolism
- Deep vein thrombosis
- Encephalopathy
- Disseminated intravascular coagulation (DIC)
- Myocardial infarction
- Superficial incisional surgical site infection
- Deep incisional surgical site infection
- Multisystem inflammatory syndrome (<18 years of age)
- HELLP syndrome
- Eclampsia
- Severe hypertension (BP>= 160/110) with acute administration of anti-hypertensive medication
- Pulmonary edema
- Hepatic rupture
- Impaired liver function (liver enzymes 2X ULN)
- Renal insufficiency (serum creatine > 1.1 mg/dL or doubling)
- Thrombocytopenia (platelets <100,000)
- Sepsis (infection with organ dysfunction)
- Bacteremia
- Endometritis requiring IV antibiotic therapy for > 24 hours
- Pelvic abscess.
- Death

[After delivery]

- Uterine packing
- Intrauterine balloon tamponade
- Uterine artery ligation
- Uterine compression sutures
- Laparotomy
- Evacuation of hematoma
- Arterial embolization
- Uterine evacuation
- Hysterectomy
- Death
- Other (specify) _____

Domain: Obstetric / Pregnancy Outcomes

Major Congenital Malformation

- Yes / No
- If yes, specify _____

Clinical Chorioamnionitis (Tier 2)

- Yes / No

Domain: Neonatal Characteristics

Sex

- M / F

Birth Weight

- in grams

Length

- in centimeters

Head Circumference (Tier 2)

- in centimeters

Neonatal COVID-19 Testing

COVID-19 Test Result

- Positive/Negative

Type of Test (Tier 2)

[Select one]

- Molecular (e.g., PCR)
- Serology (e.g., antigen, antibody)

Date(s) of Testing

- Month/Day/Year

Domain: Neonatal Outcomes

Highest Level of Care Required

[Select one]

- Well baby nursery / routine care
- NICU / intermediate nursery
- Baby died before admission to NICU
- Fetal death

Highest Level of Respiratory Support

[Select one]

- Room air, no support
- Supplemental Oxygen?
- Non-invasive intermittent positive pressure?
- Mechanical ventilation / intubation?

Neonatal Morbidities

- Mark Yes/No/Unknown to denote if the neonate had any of the following conditions:
    - Preterm delivery (<37 weeks gestation)
    - Infant received surfactant
    - Seizure
    - Pneumothorax
    - Intraventricular hemorrhage (IVH)
        - If yes, select the highest stage
            - 1, 2, 3, 4
    - Periventricular leukomalacia (PVL)
    - Pneumonia confirmed by X-ray or CT scan

- Proven early onset sepsis <=7 days
- Proven late onset sepsis >7 days
- Proven NEC
- Retinopathy of prematurity
    - If yes, select the highest stage:
        - I, II, III, IV, V
- Was infant transfused with PRBC
- Phototherapy for hyperbilirubinemia
- Hypotension requiring pressor support
- Hypoxic-ischemic encephalopathy
- Meconium aspiration syndrome
- Respiratory distress syndrome (RDS)
- Transient tachypnea of the newborn (TTN)
- Other (specify) _____

Antiviral Medications

- Mark yes/ no/ unknown to denote if the patient received any of the following COVID-19 treatments.
- *Please note that these options reflect the available treatments in October 2020. Please expand this list as necessary as treatment regiments evolve*
    - Oseltamivir
    - Tamiflu, Zanamavir
    - Relenza
    - Peramivir
    - Other (specify)

Final Status of Infant

- Stillbirth?
    - Yes / No
- Infant death?
    - Yes / No
- Date of death
    - Month/day/year
- If infant died, cause of death (time frame: up to a year)
    - Select one *primary cause* of death:
        - COVID-19
        - Congenital anomaly
        - Extreme prematurity
        - Sepsis not related to COVID-19
        - Lethal chromosome abnormality
        - HIE
        - Other (specify) _____
    - Select one *secondary* cause of death:
        - COVID-19

    - Congenital anomaly
    - Extreme prematurity
    - Sepsis not related to COVID-19
    - Lethal chromosome abnormality
    - HIE
    - Other (specify) _____
- Select all that apply for any *additional* causes of death:
    - COVID-19
    - Congenital anomaly
    - Extreme prematurity
    - Sepsis not related to COVID-19
    - Lethal chromosome abnormality
    - HIE
    - Other (specify) _____

A3. Psychosocial Key Scientific Questions

1. What are the mental health effects of the COVID-19 pandemic on pregnant women across the population and vulnerable subgroups?
2. What are mitigating factors for mental health consequences in pregnancy?
3. Does SARS-CoV2 infection of the pregnant woman disrupt mother-infant bonding? (And do hospital separation practices mediate this effect?)
4. How is instability due to the pandemic leading to or exacerbating domestic violence?
5. How are other pandemic stressors (e.g., financial strain, remote schooling, etc.) affecting mother / baby outcomes?

COVID-19 Pregnancy Registry | Psychosocial Recommended Measures

A hierarchical approach was used to select the recommended measures herein, with top preference for 1) known, validated instruments, followed by 2) measures from COVID-19 studies already in the field, 3) modified versions of existing measures, and 4) developing our own measures.

A subset of measures included here are designated as "Tier 2." Those without this designation—i.e., "Tier 1" measures—are recommended for all studies that may include women of reproductive age and pregnant women. Tier 2 measures are suggested additional measures for studies focused exclusively on COVID-19 in pregnancy and/or for any study interested in taking a "deeper dive" in certain domains.

Footnotes provide the source for each measure; the original validated measure was used where appropriate and language was updated as needed. In some instances, the working group was unable to find an appropriate validated measure and instead provided a Working Group Recommendation.

Note: Elements written in blue were added/updated by WG on July 2021.

Domain: Socioeconomic Status, Housing, and Emergent Financial Strain

Education Level

- What is the highest grade or level of school you have completed or the highest degree you have received?[8]
    - Never attended / Kindergarten only
    - 1st grade
    - 2nd grade
    - 3rd grade
    - 4th grade
    - 5th grade
    - 6th grade
    - 7th grade
    - 8th grade
    - 9th grade
    - 10th grade
    - 11th grade
    - 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)

[8] PhenX: National Health and Nutrition Examination Survey (NHANES), Demographics Module, 2019-2020

Financial Strain / Material Hardship

- How difficult is it to meet each of the following needs for you and/or your family during this pregnancy?[9]

	Not difficult	Somewhat difficult	Very difficult
Have enough money for food			
Have enough money to pay for electricity or heating or water			
Have enough money to pay for housing			
Get help from community organizations that you trust			
Get help from family members and friends			
See a healthcare provider if you or your family needs it			
Get routine / essential medications			
Get transportation when you need it			
Use the internet for things like work, school, medical visits, socializing			

- Thinking about the future, over the next 3 months, because of coronavirus, how challenging will it be to make ends meet?[10]
    - A lot more challenging than usual
    - A little more challenging than usual
    - No more challenging than usual
    - Don't know

[9] Stanford COVID-19 Community Outcomes (COCO) Survey

[10] Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH)

Postpartum Only

- How difficult is it to meet each of the following needs for you and/or your family after your recent pregnancy?[11]

	Not difficult	Somewhat difficult	Very difficult
Have enough money for food			
Have enough money to pay for electricity or heating or water			
Have enough money to pay for housing			
Get help from community organizations that you trust			
Get help from family members and friends			
See a healthcare provider if you or your family needs it			
Get routine / essential medications			
Get transportation when you need it			
Use the internet for things like work, school, medical visits, socializing			

Household Income

- Thinking about members of your family living in this household, *about how much* is your combined annual income, meaning the total pre-tax income from all sources earned in the past year?[12] *If you are not sure, make your best guess.*
    - $0 to $9,999
    - $10,000 to $14,999
    - $15,000 to $19,999

[11] Stanford COVID-19 Community Outcomes (COCO) Survey

[12] Columbia COVID-19 Questionnaire

- $20,000 to $34,999
- $35,000 to $49,999
- $50,000 to $74,999
- $75,000 to $99,999
- $100,000 to $199,999
- $200,000 or more

Government Assistance

- As a result of COVID-19 have you received[13]:

	Yes	No	Not sure	Decline to answer
Enrollment in the Special Supplemental Nutrition Program for Women, Infants, and Children, known as WIC?				
One or more stimulus checks from the government?				
Any amount of unemployment benefits from the government?				

Loss / Change of Housing

- Has the coronavirus pandemic led to any of the following?[14]

	Yes	No
Relocation or moving from where you lived before the pandemic (e.g., downsizing, moving in with family, etc.)		
Facing possible eviction		
Becoming homeless		

Household Crowding (Tier 2)

- How many total people (adults and children) currently live in your household, including yourself?[15]
  - Please enter a number _____

[13] Psychosocial Working Group Recommendation
[14] MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire
[15] 2020 COVID-19 Household Pulse Survey

- How many people under 18 years old currently live in your house, including yourself?[16]
    - Please enter a number____
- How many bedrooms are in the place where you currently live?[17]
    - Please enter a number. If you live in a place that does not have separate rooms or bedrooms, please enter "0" _____

Food Security

The following are several statements that people have made about their food situation. Please tell me whether the statement was often, sometimes, or never true for (you / you and other members of your household) in the last 12 months, since (date 12 months ago)[18]

- 1. "The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more."
    - Often true
    - Sometimes true
    - Never true
    - Don't know

- 2. "(I/we) couldn't afford to eat balanced meals."
    - Often true
    - Sometimes true
    - Never true
    - Don't know

- 3. In the last 12 months, since (date 12 months ago) did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food? [19]
    - Yes
    - No (Skip to 5)
    - Don't know (Skip to 5)

    - ***If yes, please answer the following question. If no, skip to question 5 below***
      3a. How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months? [20]
        - Almost every month
        - Some months but not every month
        - Only 1 or 2 months
        - Don't know

- 4. In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food? [21]

[16] 2020 COVID-19 Household Pulse Survey
[17] Psychosocial Working Group Recommendation
[18] 6-item Standard Measure from USDA Economic Research Service
[19] PhenX: 6 item standard measure from USDA Economic Research Service
[20] PhenX: 6 item standard measure from USDA Economic Research Service
[21] PhenX: 6 item standard measure from USDA Economic Research Service

- Yes
- No
- Don't know

- 5. In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food? [22]
  - Yes
  - No
  - Don't know

End of 6-Item Standard Measure from USDA Economic Research Service

- In the last 12 months, if you didn't have enough to eat or what you wanted to eat, why was that? Choose all that apply.[23]
  - Couldn't get out to buy food (for example, didn't have transportation, or had mobility or health problems that prevented you from getting out)
  - Afraid to go or didn't want to go out to buy food
  - Afraid to go out because of the chance of contracting COVID-19
  - Couldn't get groceries or meals delivered to me
  - The stores didn't have the food I wanted
  - Other (specify)?
  - I always had enough to eat and what I wanted to eat

Current Employment

- What is your current employment situation?[24]
  - Working now
  - Only temporarily laid off, sick leave, or maternity leave
  - Looking for work, unemployed
  - Retired
  - Disabled, permanently, or temporarily
  - Keeping house / home maker / stay at home parent
  - Student
  - Other (specify): _____

Changes in Employment Situation

- Which of the following changes in employment have occurred due to the COVID-19 outbreak? (Check all that apply)[25]

	Self			Partner		
	Yes	**No**	**N/A**	**Yes**	**No**	**N/A**
(1) Move to remote work, telework						
(2) Loss of hours						
(3) Decreased pay						

[22] PhenX: 6 item standard measure from USDA Economic Research Service
[23] Psychosocial Working Group Recommendation
[24] PhenX: Panel Study of Income Dynamics (PSID), 2007
[25] Adapted from Coronavirus Perinatal Experiences-Impact Survey (COPE-IS)

(4) Loss of job						
(5) Decreased job security						
(6) Disruptions due to childcare challenges						
(7) Increased hours						
(8) Another change						

- How bothersome or distressful were changes to your family's employment?[26]
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

COVID-19 Exposure Risk due to Occupation

- Does your job or occupation require you to be in person and face-to-face with others?[27]
  - Yes
  - No

➢ ***If yes, please answer the following questions. If no, please skip to the next section.***

Are you able to practice physical distancing at work (stay at least 6 feet away from other[28] people)?
  - Yes
  - No
  - Sometimes

Do you consistently use Personal Protective Equipment (PPE) (like a mask or face shield or gloves) you need to limit your exposure to the coronavirus in your workplace? [29]
  - Yes
  - No

Zip Code

- What is the zip code where you currently live?[30]

Domain: Healthcare access

Health Insurance Status

- Are you currently covered by any of the following types of health insurance or health coverage plans?[31] (Please exclude plans that pay for only one type of service—such as, nursing home care, accidents, family planning, or dental care—and plans that only provide extra cash when hospitalized)

	Covered	Not Covered	Not Sure

[26] Adapted from JHU Community Response
[27] Psychosocial Working Group Recommendation
[28] Psychosocial Working Group Recommendation
[29] Psychosocial Working Group Recommendation
[30] Stanford COVID-19 Community Outcomes (COCO) Survey
[31] PhenX – Health Reform Monitoring Survey 2015

a. Insurance through a current or former employer or union (of yours or another family member's). This would include COBRA coverage.	1	2	3
b. Insurance purchased directly from an insurance company (by you or another family member). This would include coverage purchased through an exchange or marketplace, such as HealthCare.gov [IF THE RESPONDENT IS IN A STATE WITH STATE-SPECIFIC NAMES, INSERT [or (INSERT PROGRAM NAME)]].	1	2	3
c. Medicare, for people 65 and older, or people with certain disabilities.	1	2	3
d. Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-sponsored assistance. plan based on income or a disability. You may know this type of coverage as [IF THE RESPONDENT IS IN A STATE WITH STATE-SPECIFIC NAMES INSERT PROGRAM NAME].	1	2	3
e. TRICARE or other military health care, including VA health care.	1	2	3
f. Indian Health Service.	1	2	3
g. Any other type of health insurance. coverage or health coverage plan	1	2	3

Changes to Health Insurance (Tier 2)

- During this pregnancy have you had a change in your health insurance coverage?[32]
    - Yes
    - No

    - ***If yes, please answer the following question. If no, no further questions for this data element***
      What change occurred?
        - Loss of your health insurance
        - Fewer benefits / less coverage from the insurance
        - Gaining insurance, for example as part of emergency coverage of Medicaid expansion[33]

[32] MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire

[33] Psychosocial Working Group Recommendation

Access to Medical Care

- During this pregnancy, has the coronavirus led to any of the following changes in your prenatal care or problems accessing medical care? If yes, was it because… (select all that apply)[34]
    - My healthcare provider canceled some or all of my prenatal visits
    - I had more prenatal visits
    - My prenatal visits changed from in-person to phone or telemedicine/video
    - I could not afford to pay for care
    - I was scared I might get infected with the coronavirus at the health care facility
    - The healthcare facility was closed because of the coronavirus pandemic
    - I had symptoms of COVID-19, so I stayed home
    - I cancelled the appointment(s) to avoid being around others
    - I cancelled the appointment because I did not want to be in a healthcare setting
    - I felt okay or good enough and didn't need care
    - I had difficulty arranging childcare and couldn't attend prenatal care visit(s)
    - I had no transportation to get to the healthcare provider's office
    - I had no one to go with me or help me during appointments
    - I was scared I might get infected with the coronavirus on public transportation
    - I forgot to go / just missed my appointment
    - Changed format of prenatal care (i.e. no group classes)[35]
    - Cancellation of hospital tours[36]

Postpartum Only

- Since you gave birth, has the coronavirus led to any of the following problems accessing medical care?
    - Yes
    - No

    - ***If yes, please answer the following question. If no, no further questions for this data element***

      Was it because… (select all that apply)[37]
    - I could not afford to pay for care
    - I was scared I might get infected with the coronavirus at the health care facility
    - The healthcare facility was closed because of the coronavirus pandemic
    - I had difficulty arranging childcare
    - I had no transportation to get to the healthcare provider's office
    - I was scared I might get infected with the coronavirus on public transportation
    - My provider switched to telehealth visits
    - I had no one to go with me or help me

Distress about changes to Medical Care (Tier 2)

- How bothersome or distressful were those changes to prenatal care and problems accessing medical care?[38]

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[34] Adapted from MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire
[35] Coronavirus Perinatal Experiences-Impact Survey (COPE-IS)
[36] Coronavirus Perinatal Experiences-Impact Survey (COPE-IS)
[37] MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire
[38] JHU Community Response

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Changes to Delivery Plan due to COVID-19 (Tier 2)

- Which of the following changes did you experience as a result of the COVID-19 outbreak? *(Mark all that apply)*[39]
  - I changed from planning a vaginal birth to a C-section
  - My planned C-section or labor induction was changed
  - I delivered in the hospital instead of at home
  - I delivered at home instead of in the hospital
  - My support people (e.g., spouse/partner, family) were not permitted to attend delivery or visit after delivery
  - I didn't get to have skin to skin contact right after baby was born[40]
  - I was separated from my baby immediately after delivery, to avoid exposure because I had COVID-19[41]
  - I was not able to room-in with the baby[42]
  - I changed from planning to breastfeeding to feeding only formula
  - I changed from planning to feed only formula to breastfeeding
  - Nothing changed in my prenatal care, birth or newborn plans

Distress About Changes to Delivery Plan (Tier 2)

- How bothersome or distressful was that experience?[43]
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

Domain: Impact on Parenting

Breastfeeding

- What method do you plan to use to feed your new baby in the first few weeks?[44]
  - Breastfeed only (baby will not be given formula)
  - Formula feed only
  - Both breast and formula feed
  - Don't know yet

- Were you ever advised you should not breastfeed you new baby(ies), for example if you have a health condition that prevents it?[45]

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[39] Environmental Influences on Child Health Outcomes (ECHO) COVID-19 Questionnaire
[40] Psychosocial Working Group Recommendation
[41] Psychosocial Working Group Recommendation
[42] Psychosocial Working Group Recommendation
[43] JHU Community Response
[44] Infant Feeding Practices Study II
[45] Psychosocial Working Group Recommendation

- Yes
- No
- Don't know

Postpartum only

- Did you ever breastfeed or pump breast milk to feed your new baby (or babies if you had twins or more) after delivery, even for a short period of time?[46] *(If mother has multiple babies, direct the mother to answer based on the baby they breastfeed the most)*
  - Yes
  - No

Feelings of Attachment to Newborn

Postpartum Only

- Please indicate how often the following are true for you. There are no 'right' or 'wrong' answers. Choose the answer which seems right in your recent experience:[47]

	Always	Very often	Quite often	Some-times	Rarely	Never
I feel close to my baby	0	1	2	3	4	5
I wish the old days when I had no baby would come back	5	4	3	2	1	0
The baby doesn't seem to be mine	5	4	3	2	1	0
My baby winds me up	5	4	3	2	1	0
I love my baby to bits	0	1	2	3	4	5
I feel happy when my baby smiles or laughs	0	1	2	3	4	5
My baby irritates me	5	4	3	2	1	0
My baby cries too much	5	4	3	2	1	0
I feel trapped as a mother	5	4	3	2	1	0
I resent my baby	5	4	3	2	1	0
My baby is the most beautiful baby in the world	0	1	2	3	4	5
I wish my baby would somehow go away	5	4	3	2	1	0

Impact of Pandemic on Children's Education (Tier 2)

- Do you have children living in your home that you are responsible for?[48]
  - No
  - Yes
  - ➢ ***If yes, please answer the following questions. If no, move on to next question.***
    How many? _____
    What is the age of the youngest child? _____ Years

[46] PhenX: Pregnancy Risk Assessment Monitoring System (PRAMS)
[47] Postpartum Bonding Questionnaire
[48] Study of Pregnancy and Neonatal Health (SPAN) – Attained measures via personal communication

What is the age of the oldest child? _____ Years

- What is your household's current situation for childcare and/or schooling? (select all that apply)[49]
    - I or someone in my household care for my child(ren) full-time
    - I or someone in my household care for my child(ren) part-time
    - I or someone in my household try to balance childcare/home schooling and work/telework responsibilities at home
    - Someone from outside my household (friend, family, nanny) cares for my child(ren) in my home
    - My child(ren) goes to a childcare center or someone else's home for childcare
    - My child(ren) does not need childcare; they take care of themselves
    - My child(ren) goes to school in-person
    - My child(ren) goes to school virtually (online)

Distress About Impact of Pandemic on Children's Education (Tier 2)

- How bothersome or distressful is the current situation for childcare and/or schooling?[50]
    - Not at all
    - A little bit
    - Somewhat
    - Quite a bit
    - Very much

Impact of Pandemic on Childcare

- How has the COVID-19 outbreak affected your regular childcare? (Mark all that apply)[51]
    - I had difficulty arranging for childcare
    - I had to pay more for childcare
    - My spouse/partner or I had to change our work schedule to care for our children ourselves
    - My regular childcare has not been affected by the COVID-19 outbreak
    - I do not have a child in childcare.

Distress About the Impact of the Pandemic on Childcare (Tier 2)

- How bothersome or distressful have the changes to your regular childcare been?[52]
    - Not at all
    - A little bit
    - Somewhat
    - Quite a bit
    - Very much
    - My regular childcare has not been affected by the COVID-19 outbreak
    - I do not have a child in childcare

[49] Study of Pregnancy and Neonatal Health (SPAN) – Attained measures via personal communication
[50] JHU Community Response
[51] Environmental Influences on Child Health Outcomes (ECHO) COVID-19 Questionnaire
[52] JHU Community Response

Domain: Stressful Life Events

Racial / Ethnic Harassment and Discrimination

- In your day to day life, how often do any of the following things happen to you?[53]

	Almost everyday	At least once a week	A few times a month	A few times a year	Less than once a year	Never
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.						

➢ ***Please answer the below question for each experience that you marked as "A few times a year" or more. If you did not answer "A few times a year" or more to any question, no further questions for this data element***

What do you think is the main reason for these experiences (Check all that apply)[54]

- Your ancestry or national origins
- Your gender
- Your race
- Your age
- Your religion
- Your height
- Your weight
- Some other aspect of your physical appearance
- Your sexual orientation
- Your education or income level
- A physical disability
- Your shade of skin color
- Your tribe
- Other (specify) _____

[53] Everyday Discrimination Scale (Short version)

[54] Everyday Discrimination Scale (Short version)

Intimate Partner Violence

- "Has your current partner ***ever*** threatened you or made you feel afraid?" (For example, threatened to hurt you or your children if you did or did not do something, controlled who you talked to or where you went, or gone into rages)[55]
    - No
    - Yes
- Has your partner ***ever*** hit, choked, or physically hurt you?
    - No
    - Yes
- Has your partner ***ever*** forced you to do something sexually that you did not want to do, or refused your request to use condoms?
    - No
    - Yes
- Does your partner support your decision about when or if you want to become pregnant?
    - No
    - Yes
- Has your partner ***ever*** tampered with your birth control or tried to get you pregnant when you didn't want to be?
    - No
    - Yes

Now I would like to ask you some questions about experiences with your partner or spouse. ***In the last 12 months***, how often has a partner or spouse…[56]

- Yelled at you or said things to you that made you feel bad about yourself, embarrassed you in front of others, or frightened you?
    - Never
    - Almost never
    - Sometimes
    - Fairly often
    - Very often

- Done things like push, grab, hit, slap, kick, or throw things at you during an argument or because they were angry with you?
    - Never
    - Almost never
    - Sometimes
    - Fairly often
    - Very often

Change in Frequency of Abuse (Tier 2)

- In the last 12 months has the frequency of these behaviors increased, decreased or stayed the same?[57]
    - Increased

[55] Intimate Partner Violence ACOG Practice Bulletin
[56] RAND American Life Panel Impact of COVID-19 Survey
[57] RAND American Life Panel Impact of COVID-19 Survey

- Decreased
- Stayed the same

Domain: Mental health/stress (including resilience factors)

Antepartum / Postpartum Depression

In the past 7 days:[58]

- I have been able to laugh and see the funny side of things
  - 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
  - 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 went wrong
  - 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
  - No, not at all
  - Hardly ever
  - Yes, sometimes
  - Yes, very often

- I have felt scared or panicky for no very good reason
  - Yes, quite a lot
  - Yes, sometimes
  - No, not much
  - No, not at all

- Things have been getting on top of me
  - 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, have been coping as well as ever

- I have been so unhappy that I have had difficulty sleeping
  - Yes, most of the time

[58] PhenX: Edinburgh Postnatal Depression Scale (EPDS)

- Yes, sometimes
- Not very often
- No, not at all

- I have felt sad or miserable
  - 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
  - Yes, most of the time
  - Yes, quite often
  - Only occasionally
  - No, never

- The thought of harming myself has occurred to me
  - Yes, quite often
  - Sometimes
  - Hardly ever
  - Never

COVID-19 Related Anxiety

Below is a list of difficulties people sometimes have after stressful life events. Please read each item and then indicate how distressing each difficulty has been for you.[59]

- **DURING THE PAST SEVEN DAYS** with respect to the COVID-19 pandemic, how much were you distressed or bothered by these difficulties?

	Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
1. Other things kept making me think about it.	O	O	O	O	O
2. I thought about it when I didn't mean to.	O	O	O	O	O
3. I tried not to think about it.	O	O	O	O	O
4. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	O	O	O	O	O
5. I had trouble concentrating.	O	O	O	O	O
6. I felt watchful and on-guard.	O	O	O	O	O

General Anxiety Disorder Symptoms

- Over the last **2 weeks**, how often have you been bothered by the following problems?[60]

	Not at all	**Several days**	**Over half the days**	**Nearly every day**

[59] Impact of Event Scale-6
[60] GAD 7

Feeling nervous, anxious, or on edge				
Not being able to stop or control worrying				
Worrying too much about different things				
Trouble relaxing				
Being so restless that it's hard to sit still				
Becoming easily annoyed or irritable				
Feeling afraid as if something awful might happen				

Coping Mechanisms

- What have you done to cope with your stress related to the COVID-19 outbreak? (Mark all that apply)[61]
    - Meditation and/or mindfulness practices
    - Talking with friends and family (e.g., by phone, text, or video)
    - Engaging in more family activities (e.g., games, sports)
    - Increased television watching or other "screen time" activities (e.g., video games, social media)
    - Getting exercise
    - Eating more often, including snacking
    - Increasing time reading books, or doing activities like puzzles and crosswords
    - Going outside, enjoying nature and the outdoors
    - Drinking alcohol
    - Using tobacco (e.g., smoking, vaping)
    - Using marijuana (e.g., vaping, smoking, eating) or cannabidiol (CBD)
    - Talking to my healthcare providers more frequently, including mental healthcare provider (e.g., therapist, psychologist, counselor)
    - Volunteer work
    - I have not done any of these things to cope with the COVID-19 outbreak

[61] Environmental Influences on Child Health Outcomes (ECHO) COVID-19 Questionnaire

- These items deal with ways you've been coping with the stress in your life since the onset of the coronavirus pandemic. Consider how well the following statements describe your behavior and actions. [62]

	Does not describe me at all	Does not describe me	Neutral	Describes me	Describes me very well
I look for creative ways to alter difficult situations.	1	2	3	4	5
Regardless of what happens to me, I believe I can control my reaction to it	1	2	3	4	5
I believe I can grow in positive ways by dealing with difficult situations	1	2	3	4	5
I actively look for ways to replace the losses I encounter in life.	1	2	3	4	5

Sources of Support

- In the **past month**, has there been someone you can talk to about things that are important to you – someone you can count on for understanding or support? [63]
    - Very infrequently
    - Infrequently
    - Neutral
    - Frequently
    - Very frequently

In the **past month**, please describe how often...[64].

- There is someone around to help you if you need it (like taking you to the doctor, taking you grocery shopping, or making meals, watching your kids)
    - Never
    - Rarely
    - Sometimes

[62] Brief Resilient Coping Scale
[63] MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire
[64] Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH)

- Usually
- Always
- Don't Know

- Do you have someone who you can depend on in an emergency (going into labor, Emergency expense of more than you can afford? [65]
  - Definitely
  - Most likely
  - Unsure
  - Most likely not
  - Definitely not

Loneliness / Social Isolation (Tier 2)

- How often do you feel that you lack companionship: Hardly ever, some of the time, or often?[66]
  - Hardly Ever
  - Some of the Time
  - Often
- How often do you feel left out: Hardly ever, some of the time, or often? [67]
  - Hardly Ever
  - Some of the Time
  - Often
- How often do you feel isolated from others? (Is it hardly ever, some of the time, or often?) [68]
  - Hardly Ever
  - Some of the Time
  - Often

Domain: Health Related Behaviors

Pre-Pregnancy and Current Alcohol Use (Tier 2)

- In the month before you became pregnant, how often did you have a drink containing alcohol?[69]
  - Never → ***skip the next 2 questions***
  - Monthly or less
  - 2-4 times a month
  - 2-3 times a week
  - 4 or more times a week

- In the month before you became pregnant, how many standard drinks containing alcohol did you have on a typical day? (A standard drink is one 12-oz bottle/can of beer, one 5 oz glass of wine, or one 1.5 oz shot of liquor) [70]
  - 1 or 2
  - 3 or 4
  - 5 or 6

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[65] Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH)
[66] PhenX: 3-item loneliness scale, UCLA Loneliness Scale
[67] PhenX: 3-item loneliness scale, UCLA Loneliness Scale
[68] PhenX: 3-item loneliness scale, UCLA Loneliness Scale
[69] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)
[70] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)

- 7 to 9
- 10 or more

- In the month before you became pregnant, how often did you have four or more standard drinks on one occasion? (A standard drink is one 12-oz bottle/can of beer, one 5 oz glass of wine, or one 1.5 oz shot of liquor) [71]
  - Never
  - Less than monthly
  - Monthly
  - Weekly
  - Daily or almost daily

- In the **past month**, how often did you have a drink containing alcohol?[72]
  - Never → ***skip the next 2 questions***
  - Monthly or less
  - 2-4 times a month
  - 2-3 times a week
  - 4 or more times a week

- In the **past month** how many standard drinks containing alcohol did you have on a typical day? (A standard drink is one 12-oz bottle/can of beer, one 5 oz glass of wine, or one 1.5 oz shot of liquor) [73]
  - 1 or 2
  - 3 or 4
  - 5 or 6
  - 7 to 9
  - 10 or more

- In the **past month**, how often did you have four or more standard drinks on one occasion? (A standard drink is one 12-oz bottle/can of beer, one 5 oz glass of wine, or one 1.5 oz shot of liquor) [74]
  - Never
  - Less than monthly
  - Monthly
  - Weekly
  - Daily or almost daily

Current Opioid Use (Tier 2)

- In the **past month**, how frequently have you used opiates, heroin, or other narcotics? (including prescription narcotics like Vicodin and OxyContin, etc.)[75]
  - Not at all
  - Rarely

[71] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)
[72] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)
[73] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)
[74] All of Us Research Program: COVID-19 Participant Experience Survey (COPE)
[75] Coronavirus Health Impact Survey (CRISIS)

- Once a month
- Several times a month
- Once a week
- Several times a week
- Once a day
- More than once a day

Current Weekday Hours of Sleep (Tier 2)

- In the **past seven days** was your sleep was restless?[76]
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

- In the **past seven days** what was your sleep quality?[77]
  - Very poor
  - Poor
  - Fair
  - Good
  - Very good

[76] Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH)
[77] Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH)

Disaster Information
MANAGEMENT RESEARCH CENTER

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COVID-19 is an emerging, rapidly evolving situation.
Get the latest public health information from CDC: https://www.coronavirus.gov
Get the latest research information from NIH: https://www.nih.gov/coronavirus

Currently, NLM is not updating the Disaster Information Management Research Center (DIMRC) website, and is limiting updates to the **Disaster Lit** database to COVID-19 related data collection tools found in the **DR2**. We are no longer adding links to other new disaster-related information. The content of select resources from Disaster Lit will be digitized and made available through **Digital Collections** and **Bookshelf**.

The original sources for disaster-related information from Disaster Lit can be found at:

- CDC **Emergency Preparedness and Response** website
- ASPR **Public Health Emergency** website
- ASPR **Technical Resources, Assistance Center, and Information Exchange (TRACIE)** website

If you have questions or suggestions, please contact **NLM Customer Service**.

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1. Recommendations for Common Data Elements for COVID-19 Studies Including Pregnant Participants

Source: National Institute of Child Health and Human Development [National Institutes of Health]

(NICHD)

Date Published: 12/15/2020

Format: Text

Annotation: We present a battery of recommended biomedical and psychosocial common data elements (CDEs) and measures that, when combined across datasets, can improve our collective understanding of COVID-19 in pregnant and lactating women and their neonates. Experts across eight large pregnancy cohort studies developed these recommendations for use by any planned or upcoming COVID-19 study that includes women of reproductive age or pregnant women. We encourage researchers to include some or all of these measures, which cover key medical and psychosocial domains relevant to pregnancy and childbirth, into their studies to maximize the potential for data harmonization while continuing to advance their own study goals.

Common biomedical data elements and measures aim to accelerate our understanding of the clinical course of the disease and its effects on pregnant women and their neonates, which will continue to evolve as treatments and vaccines become available. Here we highlight CDEs and measures across seven domains, which include: Baseline Maternal / Pregnancy Characteristics; Maternal COVID-19 Treatment; Maternal Outcomes; Obstetric / Pregnancy Outcomes; Neonatal Characteristics; Neonatal COVID-19 Testing; and Early Neonatal Outcomes. Recommendations assume that information from all patient visits (e.g., prenatal visits, COVID-19 testing, and delivery) can be collected via medical chart or downloaded data from electronic health records.

Common psychosocial data elements and measures aim to advance our understanding of the psychological, behavioral, and social effects of the virus and the pandemic on pregnant women and their neonates. Here we highlight CDEs and measures across six domains, including: Socioeconomic Status, Housing, and Emergent Financial Strain; Medical Care; Impact on Parenting; Stressful Life Events; Maternal Mental Health; and Health Related Behaviors.

Questions Adapted From: The majority of the recommended CDEs are already in use in ongoing COVID-19 studies, as indicated below and in footnotes throughout.

Biomedical: Adapted from Maternal Fetal Medicine Unit (GRAVID) COVID-19 and Delivery Case Report Forms with additional input from the Study of Pregnancy and Neonatal Health (SPAN) and other ongoing or planned studies.

Psychosocial: The source for each question is provided in the footnotes.

A full list of sources used is as follows:

2020 COVID-19 Household Pulse Survey https://www.census.gov/data/experimental-data-products/household-pulse-survey.html;

All of Us Research Program: COVID-19 Participant Experience Survey (COPE) https://www.nlm.nih.gov/dr2/COPE_Survey_NIH_All_of_Us_Clean_4.27.20.pdf;
Brief Resilient Coping Scale (from MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire) https://www.nlm.nih.gov/dr2/MACS-WIHS_questionnaire_BLCOVID-040620.pdf;
Columbia COVID-19 Questionnaire http://www.columbiamedicine.org/divisions/kiryluk/study_covid19.php;
Coronavirus Health Impact Survey (CRISIS) https://www.nlm.nih.gov/dr2/CRISIS_Parent_Caregiver_Follow_Up_Current_Form_V0.3.pdf;
Coronavirus Perinatal Experiences-Impact Survey (COPE-IS) https://www.nlm.nih.gov/dr2/COPE-Impact_Survey_Perinatal_Pandemic_Survey.pdf;
Environmental Influences on Child Health Outcomes (ECHO) COVID-19 Questionnaire https://www.nlm.nih.gov/dr2/C19-aPV_COVID-19_Questionnaire-Adult_Primary_Version_20200409_v01.30.pdf;
Everyday Discrimination Scale (Short version) https://scholar.harvard.edu/files/davidrwilliams/files/measuring_discrimination_resource_june_2016.pdf;
GAD 7 https://med.dartmouth-hitchcock.org/documents/GAD-7-anxiety-screen.pdf;
Impact of Event Scale-6 https://www.researchgate.net/publication/26250275_Brief_measure_of_posttraumatic_stress_reactions_Impact_of_Event_Scale-6;
Infant Feeding Practices Study II https://www.cdc.gov/breastfeeding/data/ifps/questionnaires.htm;
Intimate Partner Violence ACOG Practice Bulletin https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2012/02/intimate-partner-violence ;
JHU Community Response https://www.nlm.nih.gov/dr2/JHU_COVID-19_Community_Response_Survey_v1.3.pdf ;
MACS-WIHS Baseline COVID-19 Abbreviated Questionnaire https://www.nlm.nih.gov/dr2/MACS-WIHS_questionnaire_BLCOVID-040620.pdf;
National Health and Nutrition Examination Survey (NHANES), Demographics Module, 2019-2020 https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/questionnaires.aspx?BeginYear=2019;
PhenX: Health Reform Monitoring Survey 2015 https://www.phenxtoolkit.org/protocols/view/11502;
PhenX: 6 item standard measure from USDA Economic Research Service https://www.phenxtoolkit.org/protocols/view/270301#tabsource;
PhenX: Edinburgh Postnatal Depression Scale (EPDS) https://www.phenxtoolkit.org/protocols/view/241401;
PhenX: Panel Study of Income Dynamics (PSID), 2007 https://www.phenxtoolkit.org/protocols/view/11301;
PhenX: Pregnancy Risk Assessment Monitoring System (PRAMS) https://www.phenxtoolkit.org/protocols/view/720901;
Pittsburgh Hill / Homewood Research on Neighborhood Change and Health (PHRESH) https://drive.google.com/file/d/1q9DOJGNT7oe_KGMUXFCi73vIu57W3D3O/view;

Postpartum Bonding Questionnaire https://sundspsykologerna.se/files/Brockington-et-al-2006-PBQ-validation-pdf.pdf;
RAND American Life Panel Impact of COVID-19 Survey
https://www.phenxtoolkit.org/toolkit_content/PDF/RAND_ALP_COVID19.pdf;
Stanford COVID-19 Community Outcomes (COCO) Survey https://drive.google.com/file/d/1zHnqLG-I8HtI6SdhyFxuJzP_qYRFPgKi/view;
Study of Pregnancy and Neonatal Health (SPAN)
https://www.nichd.nih.gov/about/org/diphr/officebranch/eb/SPAN: Attained measures via personal communication

Population: Adult Workers
Adults and Teens
First Responders, Emergency Medical Services (EMS) Personnel, Police/Fire Departments
Military
Pregnant or Lactating Women

Length: There are a total of 121 questions within the tool, 49 of which fall under Biomedical data elements, and 72 of which fall under Psychosocial data elements

Time to Complete: Approximately 20 minutes to complete all questions included in the Psychosocial measure.

Mode of Administration: Face-to-face
Online (e.g., computer-assisted interview)
Pen and Paper
Telephone

Administered by: Lay Interviewer
Professional Interviewer
Self Administered
Specialist/Doctor/Expert
Trained Lay Examiner/Interviewer

Special Considerations: The recommendations herein are not meant to be distributed as one comprehensive questionnaire, but rather represent the recommended measures for collecting information regarding the most important data elements to assess in relation the effects of COVID-19 on pregnant women and their neonates. We encourage researchers to include some or all of these measures into their studies to maximize the potential for data harmonization while continuing to advance their own study goals.

Language(s): English [See less]
URL: https://disasterinfo.nlm.nih.gov/content/files/Recommendations for Common Data Elements for COVID-19 Studies Including Pregnant Women.docx
Type: Guideline/Assessment Tool
Access Notes: Free/Publicly Available

Companion Report: "Promoting Data Harmonization to Accelerate COVID-19 Pregnancy Research", December 2020.
https://disasterinfo.nlm.nih.gov/content/files/Promoting%20Data%20Harmonization%20to%20Accelerate%20COVID-19%20Pregnancy%20Research.pdf

Available Formats: TEXT

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Includes Research Tools: Yes.
ID: 24206. From: Disaster Lit®a database of the U.S. National Library of Medicine.

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